B. Variations in patent scope are an additional cause for manufacturers to move to trade secret dependency.

As mentioned above, decrease in patent dependence represents a culmination of issues with patents such as increased complication of patent standards, lack of patent validity insurance, antitrust ruling eliminating financial alternatives to prevent validity litigation, dual patenting (product and process) discouragement, additional trade secret protections. Originally, federal legislation greatly favored and offered extended protection to patents over trade secrets. Patents were regulated directly through the Federal Food, Drug, and Cosmetics Act [7] and the Drug Price Competition and Patent Term Restoration Act of 1984 (the ***Hatch-Waxman*** Act), [8] and indirectly through regulations promulgated by the Food and Drug Administration (FDA). [9] Despite these protections, patent law is progressively weakening. The increasingly complicated nature of patent formation leads companies to be concerned about their standing and therefore, desire to protect it from litigation, but in a recent case, even that alternative was removed as an option.

Recent judicial decisions have weakened the protections garnered by patents. One such example is the expansion of the scope of the safe harbor provision of the Hatch-Waxman Act that allows competing drug manufacturers to "borrow" information within the patents of their competitors if it was specifically for the purpose of their own FDA submission. In the 2012 case *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* [10] the Federal Circuit held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented testing methods for pre-clinical research and manufacturing without incurring infringement liability. Although Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) litigation not only gave its competitor use of Amphastar's testing method to develop its own generic, but the litigation delay also gave the competitions generic a year to monopolize the product resulting in profits over $260 million.[10] Thus, the Federal Circuit's holding in *Momenta* threatens manufacturers of generics with a devastating loss of previously available patent protection for testing methods. *Momenta* demonstrates that the scope of the safe

harbor provision has been expanded to such an extent that protection via method patents is no longer available.

Beyond rulings that weaken or eliminate the options of method or process protections through patents, rulings have also shown granted patents may be ultimately invalidated or temporarily invalidated leading to drastic consequences for the companies that worked so hard to obtain them. In *Pfizer v. Apotex*, the plaintiff patentee was granted a judgment of infringement and injunctive relief against the defendant which manufactured a generic version of the patentee's drug Norvasc before the expiration of the term of the patent. On appeal, the generic manufacturer challenged the ruling that the patent was not invalid for obviousness. The original drug was developed with a different salt of the key ingredient, amlodipine, but the patentee determined that use of a besylate salt was superior. The generic manufacturer certified that it believed the patent was invalid and unenforceable. If the patent was upheld as valid, the product would literally infringe the claims. The district court rejected the argument that the prior art rendered the invention of the claims of obviousness. On appeal, the court found the evidence of record easily shown by clear and convincing evidence that a skilled artisan would in fact have been motivated to combine the prior art to produce the specified compound. The court declared that it would have been obvious to one skilled in the art to make amlodipine besylate. That the patentee had to verify through testing the expected traits of each acid addition salt was of no consequence. The judgment of the district court was reversed because the subject matter of the patent claims in issue would have been obvious. Ultimately, the determination is one of weight and totality of the evidence. According to the Graham Test, the weight given to the patent examiner's determination should constitute only on factual consideration in a court's consideration of the totality of the circumstances. As wonderful as bright line rules are, the variability of individual cases often require this totality of the circumstance's tests. I believe in this case it was very important because it is dangerous to rely on one person's testimony no matter their authority or specialization, so it's a good pattern to develop.

Patent's strength depends on their approval ensuring coverage. Trade Secrets do not go through the same official approval process, so they do not have the extra level of verification that they meet

the definition and qualify for the requisite protection. Unfortunately, patents have been successively limited not only in scope, but even effectively after approval. This increased recognition that patents are no longer guaranteed after verification and can later be ruled invalid has weakened one of their strongest advantages over trade secrets. Patent invalidity now represents a comparable weakness to companies' own responsibility to make sure their trade secrets meet the definition required for protections to apply.

As improper patent writing has led companies' patents to fail. Some companies attempted to circumvent litigation and rulings on the validity of their patents through agreements with the competition to respect those patents. In FTC vs. Actavis, the Supreme Court considered whether a "reverse payment" settlement agreement can sometimes unreasonably diminish competition in violation of antitrust laws. [11] For my own notation, the reverse payment agreement entails that in a situation where Company A sues Company B for patent infringement, the two companies settle on terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B millions of dollars. Requiring the patentee to pay the alleged infringer is what constitutes the reverse as well as introduces the antitrust issue of discouraging competition. The 11th Circuit believed that the only pertinent question was whether the settlement agreement falls within the legitimate scope of the patent's exclusionary potential. The Supreme Court disagreed with measuring the length or amount of restriction based solely against the length of the patent's term and earning potential, and instead considered traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances (patent litigation). Whether a restraint lies beyond the limits of patent monopoly is the conclusion from this analysis and not the starting point. The Court further explains that the price of payout can be a direct indicator of the patentee's confidence in the validity of their patent and that reverse payments are a strong indicator of higher-than competitive profits which is a strong indicator of market power. The Court explained that litigation is more feasible than believed because these cases don't require an assessment of patent liability, they would only require an antitrust analysis. At the same time, the Court refused to follow the FTC's

request that the presumption should be that these agreements are unlawful and should only receive a "quick-look" approach before ruling so. The Court ruled that the complexities of these cases require the FTC to prove its case just as in other rule-of-reason cases. Aside from the antitrust implications, this ruling effectively eliminated a possible alternative of companies to mitigate the challenges to patent validity currently plaguing the system.

Until Congress decides to narrow the scope of the Hatch-Waxman provision, the patent system allows for dual or process patents, and the patent system allows for updates to patents within their period of coverage for companies who prioritize patient care to improve their methods and products, the industry will likely continue to progress towards using trade secrets for their intellectual property protection. As trade secret litigation grows, so do the emerging issues in litigation. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect their testing methods and processes as trade secrets.

III. Trade Secret Law and the Potential Threats of Disclosure

While patent protection and the judicial system in general relies on disclosure, the trade secret protection depends on the lack of it. Therefore, proper treatment of trade secrets during litigation has led to the emergence of unique issues. Those issues include the threat of disclosure from mis definition, requests via the freedom information act, FDA use, discovery requests and the common law right of public access. including reconsideration of notification standards and the process of discovery.

A. Proper Compliance with the Definitions of Trade Secrets

Trade secrets do not require registration to qualify for trade secret protection, but their protection still depends on their ability to meet the definition and fall under its scope. Because of the nature of the product, the biotech and pharmaceutical industry still needs to pass FDA standards to be approved for medical use.

While trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA), [12] extended trade secret recognition across states. [13] The USTA provides a broad definition, defining a trade secret as "information, held by one or more people, without regard to form, including a formula . . . method . . . technique … or process that: (1) derives independent economic value … from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." [14] It is important to note that while this is the general definition under the act, each manufacturer should be mindful of state specificities that could affect the application and the scope of the trade secret protection within their state. [15] The FDA provides their own definition for trade secrets which should also be considered particularly when submitting ANDAs. [16] Similarly the FDA, defines a trade secret as, "[A]ny commercial valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." [17] Because disclosure is essential to maintenance of trade secret protection the FDA offers that they "will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information. Except where specifically exempt pursuant to the provisions of this part, all FDA records shall be made available for public disclosure." [18, 19] Based upon the emphasis of protection's dependency on definition throughout all these regulations, the courts have used these as input to develop their own definition to standardize the scope for litigation measures. The courts currently specify that, "A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process." [20] Given the consideration of the trade secret definitions provided by the UTSA, state regulations, and the FDA in conjunction with the commitment to protections of trade secrets by

each, the responsibility is therefore placed in the business' hands to ensure their own compliance to definition.

B. Information Requests Via the Freedom of Information Act and the FDA's General Disclosure Policy

One example of the importance of proper compliance with these definitions is to empower these sources of protections to withstand the common law right of public access and even specific inquiries under the Freedom of Information Act (FOIA). The Freedom of Information Act controls the public disclosure of previously unreleased information from federal agencies and coincides with common law right of public access. [21] Specific requests can be made under the act for information that was required for FDA approval as well as information recognized within litigation. [22, 23, 24] Concerningly, section 3 of the FOIA that with few exceptions, "each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person. [25] Additionally it requires the agency to perform reasonable searches for the information [26] and its findings in the format requested. [27]

While the FOIA aims to make as much agency information available to the public as possible, one of their few strict exemptions includes information that is "exempted from disclosure by statute." [28] if the statute is clear of its scope and cites to the FOIA. [29, 30] Additionally the FOIA does specify an exemption for "trade secrets and commercial or financial information obtained from a person and privileged or confidential," [31] without prior implementation in case law, manufacturers cannot be certain whether their information fits the scope of protection. This means that even a request submitted by competitors that reasonably details the information desired could lead the FDA to disclose valuable competitor information. [32] Fortunately, if the confidentiality of requested information is unknown or uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information. [33] Any FDA rejection of a FOIA request "constitutes final agency

action that is subject to judicial review" [34] and the entity requesting the information has five days after notice to file suit. [35]. If a suit is filed, the person who declared confidentiality will be required to defend their claim in court. [36]. The ruling statute reads, "If the affected person fails to intervene to defend the exempt status of the records … the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure." [36] While the defense is not mandatory, it weighs heavily on the FDA's determination of disclosure. [36] If proper compliance with the definition causes an FOIA request to be limited or rejected, the competitor can also pursue disclosure through both the common law right of public access [37] and discovery request [38] pose additional threats for generic manufacturers who wish to protect their trade secrets.

C. Right of Public Access

The common law right of public access places trade secrets in direct contention with the court's desire to maintain open records of judicial proceedings. In *Nycomed US, Inc. v. Glenmark Generics, Inc.*, the Second Circuit emphasized the importance of public access to maintain an appearance of judicial legitimacy. [39] The Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, that judicial documents are presumed to be open to public access. [40] This presumption places the burden on trade secret confidentiality on the manufacturers. In *Stern v. Cosby*, the Second Circuit determined a three-part test to be applied to trade secret cases where a judicial document may fall under the common law right of public disclosure. [41] "First, the court must determine whether the documents are indeed judicial documents … Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it." [42] The three-part test is an additional standard that, coupled with the general right to access, represents emerging issues in litigation that threatens the disclosure of trade secrets. Fortunately, the uniquely disclosure dependent nature of biotech trade secrecy means that the value of confidentiality tends to be weighed above the value of necessary public disclosure requirements. [43]

The first factor considers "whether the documents were judicial documents to which the public had a right of access." [44]Properly presented, the manufacturer could possibly end the inquiry here. The definition of "judicial documents," as discussed in Part II.C, [45] is "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies." [46] Therefore, the documents with the relevant trade secret information must be requested or submitted by the court in order for the definition to apply. The necessity of inclusion is unlikely unless the lawsuit concerns the method contained within the trade secret itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court's reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

The second factor, "the weight of the presumption of disclosure," [47] would again, if properly presented, represent a strong argument against disclosure. As the court notes, "[T]he weight of the presumption depends on the 'role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts.' " [48] Therefore, the high value of a method being kept a secret from competitors would lessen the presumption of disclosure by the court and would weigh in favor the biotech manufacturers position. Additionally, the court finds that the inquiry is often based largely on whether the information sought to be disclosed essential to the litigation. The strongest evaluation of this is if the information can be used for a motion to dismiss. [48] Thus, for the purposes of a biotech manufacturer protecting a method, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure.[48] Additionally, considering the

purpose of the doctrine, the presumption is logically stronger for information directly related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, the third factor, competing considerations against the presumption, [48] would again increase the likelihood that a biotech manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As previously mentioned, courts' disclosure of lucrative, competition-driving methods and formulas to the public during litigation, will deter biotech manufacturers who desire protection from seeking it through judicial remedies. A manufacturer's active and vigorous defense of a trade secret is itself evidence of its value in the same way as its prerequisite investments to prevent disclosure are as well. The third factor directly corresponds to the same issue of litigation that deterred manufacturers from the use of patents for protection mentioned previously. Even if public disclosure occurs via the common law right of public access, it still causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret. [49] Therefore, the presumption would favor disclosure. As demonstrated in *Momenta*, processes and methods offer a competitive advantage to generic companies who develop them, and their protection is essential to maintaining the value that incentivizes the industry overall. [49] Derogation of this incentive would cause adverse repercussions to the industry and society.

In *Nycomed*, we observe such an example. Here, the defendant sought to have the plaintiff's brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential. [50] The defendant argued that because two paragraphs of the plaintiff's motion contained confidential information related to the defendant's ANDA, this information was exempt from public disclosure. [50] The court, however, disagreed. This situation is distinguishable from one in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a method protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if

it was actually a secret. It is the very element of unique and unknown qualities trade secrets necessitate. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief. If the trade secret is correctly maintained, then it's only logical that an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place if the alleged trade secret were really a secret. The court reviewed the FDA's relevant provisions regarding the disclosure of pending ANDA's before noting that, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential." [50] Additionally the court mentioned that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access. [50] Therefore, the presumption against disclosure during litigation should be cut in favor of the generic manufacturer if the generic manufacturer treats the method information allegedly within the scope of the common law right of public access as a legitimate secret.

D. Notice Requirements and Discovery Requests

In addition to the potential for disclosure due to a competitor's assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to biotech manufacturers who seek to protect their methods. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure. [54] However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery. [55] Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,' [56] and often work together to protect parties from disclosure. [57]

As mentioned, notice requirements and discovery requests also pose a threat to manufacturers who choose to protect their methods via trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery or required during pleading to prevent summary judgment. [51] Despite this, Rules 26 and 45 are a potential avenue for biotech manufacturers to protect their method trade secrets from disclosure during these crucial steps in litigation. One such means is

through protective order. Rule 26 outlines a way in which a party may receive such a protective order from the court to guard against the disclosure of a trade secret [52]: "The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action." [52] Additionally, the rule states, "the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" by several following methods. [52] One such method includes: "requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way." [53] Although there is no *per se* protection of trade secrets in the Federal Rules of Civil Procedure, if the party seeking protection accepts the burden of proof and argues that the information should not be disclosed via Rule 26 and should be granted a protective order, the avenue of protection is maintained.

In *Massey Coal Services, Inc.*, the court elaborated on which circumstances would allow a court to issue a protective order pursuant to Rule 26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation. [58] The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation. [58] According to the claim, the defendants manufactured and installed piping that the plaintiff used in its coal mines; when the pipes failed, the defendants admitted there was a problem but would not provide further information. [58] Before the hearing, the judge issued a protective order for "documents or other materials … subject to disclosure … [that are] confidential and should not be disclosed other than in connection with this action." [58] Pursuant to the protective order the defendant proceeded to disclose to the plaintiffs several documents marked 'CONFIDENTIAL', several of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Since the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority. [58] The defendant objected, invoking protection from Rule 26(c)(1)(G) [58] and arguing that the documents contained

commercially valuable information. [58] For the purposes of analysis, the court noted that Rule 26(c)(1) "treats equally a trade secret or other confidential commercial information."

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1), [58] but the reasoning of the court indicated crucial aspects of consideration for circumstances that would allow the opposite finding including instances that did not represent a public safety concern. Overall, the courts analysis is extremely valuable in understanding the scope of the protection offered under 26(c)(1). Accordingly, in order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show "good cause" for protection, including, most relevantly, "undue burden or expense." [59] In other words, the defendants in this case argued that good cause was in the "severe economic damage" prevented by avoiding disclosure.[60] The court noted, "Broad allegations of harm, unsubstantiated by specific examples … do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle." [60] Additionally, the court recognized that defendants did not show full compliance with the trade secret standard because they failed to present any evidence that specific efforts were made to maintain the trade secrets, [60] object to disclosure of the documents to the plaintiffs, consider that the documents were contained in the court's public record, or failed to file a motion to seal the documents. [60] Therefore, the court reasoned that the documents were not compliant with trade secret standards and thus were not commercially valuable or protectable. [60] The trial judge specifically mentioned that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure. [60]

The *Massey* court's holding and reasoning showed that if a biotech manufacturer protecting a method via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense." [61] Additionally, the biotech manufacturer must argue and present evidence that meets a certain level of specificity. In other words, they should provide the court with "specific examples or articulated reasoning" [62] to show that disclosure of the trade secret

would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle." [62] The Restatement of Torts provides some valuable factors commonly used to measure secrecy that would be a valuable resource towards meeting this standard. Such factors can include:

"[T]he extent to which the information is known by employees and others involved in the business … the extent of measures taken by the business to guard the secrecy of the information … the value of the information to the business and to its competitors … and the amount of effort or money expended in developing the information." [63]

Again, since methods take substantial time, effort, and funding to create, they are critical to any biotech manufacturer's market competitiveness and often represent greater value than the product itself because of their ability to apply to multiple products. [64] This increased value should heighten the importance of their protection. Biotech manufacturers should therefore heighten their consideration and implement higher measures and care to maintain their secrecy. Steps such as increase technological security, restriction of employee access, restriction of employees to specific subject matter, confidentiality agreements or noncompete agreements are just a few ways that can not only ensure greater protection of the trade secrets in general, but also incur a greater weight to the value of the trade secrets when it comes to the consideration by the courts. The more investments taken, the more value represented and the increased likelihood that privilege and confidentiality can be established allowing for greater protection throughout litigation.

E. Subpoenas

While Rule 26 combats general disclosure, Rule 45 is considered a way to prevent wrongful disclosure during discovery by protecting trade secrets from subpoenas. Rule 45 states, "To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information … " [65] In subsequent case law where a court is deciding whether to

quash a subpoena which seeks information marked as a trade secret, "a court must evaluate all the circumstances and balance, inter alia, the requesting party's need for the information and the potential prejudice imposed on the requested party." [66] The court also considers "the relevance of the discovery sought, the requesting party's need, and the potential hardship to the party subject to the subpoena." [67]

In addition, Rule 45 of the Federal Rules of Civil Procedure, [68] which governs subpoenas, could also benefit a biotech manufacturer seeking to protect a method through trade secret law during litigation. A manufacturer's trade secret will lose its value if disclosed; given the increased value of biotech methods currently observed in the industry, biotech manufacturers should understand the risks attributed to potential subpoenas so that they can preemptively prepare for the potential need to demonstrate, if necessary, why a method trade secret should not be disclosed. When determining whether to quash a subpoena that could potentially pose a threat of disclosure to a manufacturer's method trade secret, the court will balance the burden of disclosure with the potential need for the information argued in litigation. [69]

Although there is also no *per se* protection for trade secrets under Rule 45, it is likely that a manufacturer would be able to withstand disclosure of a method in the event of a subpoena. For example, *In re Fosamax* demonstrated that biotech manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued the defendant drug company, *Merck & Co.*, alleging that a drug they manufactured, Fosamax, caused adverse side effects.[70] The court issued a subpoena at the behest of the plaintiffs to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the guidance of the FDA.[70] Dr. Psaty stated that he never studied the drug in question and moved to quash the subpoena under Rule 45(d)(3)(B).[70] [71] Additionally, the defendant argued that allowing Dr. Psaty testimony was an uncertain and unnecessary risk to the potential disclosure of confidential information or trade secrets.[71] In response, the court balanced the burden between necessity of the testimony and the undue burden on the defendant to produce the information and ultimately quashed the subpoena. [71] The court further considered whether there is an undue burden on the defendant and assessed the personal hardship to the party protecting the information as well as

the wider social consequences of disclosing the information. [71] Here, the court noted that if Dr. Psaty were required to testify, "the resulting social impact would be far more serious. Compelling testimony from a third-party researcher risks chilling participation in beneficial public research." [71] Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

When comparing this case with the potential disclosure of a biotech manufacturer's method, manufacturers who receive subpoenas would rarely if ever be required to disclose trade secrets if called to testify. Even if the testimony sought had important implications to the case's subject matter or overall determination, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the individual biotech manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage and the industry would undergo similar repercussions to the rulings that led to the deterrence of trade secret use already discussed. [72] This time, possibly more severe without an alternative option currently in existence for biotech manufacturers to turn to. In addition, requiring biotech manufacturers to disclose trade secrets would not only have a chilling effect on beneficial scientific research and disincentivizing the investment, but could also have a much wider social impact that would weigh in favor of suppressing the subpoena for risk of unforeseen consequences.

Although trade secret law does not provide per se protection from disclosure, [73] biotech manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and the notice requirements, discovery, and public right to information emerging from litigation. Although FOIA encourages the broad disclosure of information obtained by a government agency or judicial body, a biotech manufacturer can demonstrate to the FDA's FOIA office that method trade secrets are immune from disclosure. The biotech manufacturer can point to the definition of trade secret adopted in Public Citizen Health to argue that the information qualifies as a trade secret, exempting it from disclosure. The FDA's

restriction to only disclosing protected information submitted to it by a third party under limited circumstances, provides biotech manufacturers with an avenue to combat the threat of disclosure from the FDA's one potential use. If the FDA recognizes that their power of disclosure is limited by and weighed against the property interest biotech manufacturers hold in their method trade secrets, and as long as biotech manufacturers properly comply with the FDA qualification standards for what constitutes a trade secret, the threat of disclosure by the FDA is manageable. Finally, threats of disclosure and emerging litigation issues, such as the common law right of public access, notice requirements, and discovery requests made by parties to a litigation, can also be overcome by biotech manufacturers in the ways outlined. The three-part test developed by the Second Circuit in *Stern v. Cosby* demonstrates that the judicial system's presumption favoring disclosure present in the common law right of public access can be avoided by biotech manufacturers protecting methods as trade secrets. Furthermore, biotech manufacturers could also protect their method trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. Therefore, these avenues demonstrate that despite the emerging issues in the use of trade secrets over patent protection, biotech manufacturers could successfully rely on trade secrets to protect their research and development investments from competitors in ways patent law has not yet allowed.

IV. Conclusion

In summation, as argued by the dissent in Momenta that holdings and similar ones have used the safe harbor provision of the Hatch Waxman Act to render all patents on testing methods worthless, [74] an effect confirmed by later proceedings. [75] In light of the Momenta holding and other noted cases, opportunities for manufacturers to protect their intellectual property that constitutes methods or processes from use by their competitors has been removed from patent law. Fortunately, recently federalized protections for trade secrets are proving to be a viable alternative to patent protection for biotech and pharmaceutical manufacturers until Congress decides to act against these dangerous precedents. Therefore, biotech

manufacturers' increased dependence employs greater understanding and resolution of the issues that trade secret reliance has identified.

These emerging issues include the threat of disclosure from FOIA requests that can be prevented by proper compliance with the definitions set forth by statute and agencies, the threat of disclosure by the FDA's own use of information by limiting it through the second circuit's three-part test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, biotech manufacturers can protect their trade secrets by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas. Therefore, trade secret law is a viable and stable alternative to patent protection for biotech and pharmaceutical manufacturers.

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17. 21 C.F.R. § 20.61.

18. *Id.* § 20.20(a).

19. *Id.* § 20.20(b).

20. 21 C.F.R. § 20.61(a).

21. *What is FOIA*, FOIA.GOV, *http://www.foia.gov/about.html* (last visited Nov. 27, 2021).

22. Pub. L. No. 89-487,80 Stat. 250 (1967) (codified at 5 U.S.C. § 552).

23. 5 U.S.C. § 552(a)(1)(A)-(E) (2012).

24. *Id.* § 552(a)(2)(A).

25. *Id.* § 552(a)(3) (emphasis added).

26. *Id.* § 552(a)(3)(C).

27. *Id.* § 552(a)(3)(B).

28. *Id.* § 552(b)(3) (*id.* § 552(b)(3)(A)(i)-(ii); (B))).

29. *Id.* § 552(b)(3)(A)(i)-(ii).

30. *Id.* § 552(b)(3)(B)

31. *Id.* § 552(b)(4).

32. *Id.* § 20.40(b)(2).

33. *Id.* § 20.47.

34. *Id.* § 20.48.

35. *Id.* § 20.48.

36. 21 C.F.R. § 20.55.

37. *Stern v. Cosby,* 529 F. Supp. 2d 417 (S.D.N.Y. 2007).

38. *Massey Coal Services, Inc. v. Victaulic Co. of Am.,* 249 F.R.D. 477 (S.D. W. Va. 2008).

39. *Nycomed US, Inc. v. Glenmark Generics, Inc.*, No. 08-CV-5023 (CBA), 2010.

40. 435 F.3d 110, 122 (2d Cir. 2006). (quoting *FTC v. Standard Fin. Mgmt. Corp.,* 830 F.2d 404, 409 (1st Cir. 1987))

41. *Stern v. Cosby,* 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007).

42. *Nycomed US, Inc. v. Glenmark Generics, Inc.,* 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.).

43. FED. R. CIV. P. 26(c)(1)(G);

44. FED. R. CIV. P. 26(c)(1)(G); id. § 45(d)(3)(B).

45. *Nycomed US, Inc. v. Glenmark Generics, Inc.*, No. 08-CV-5023(CBA), *2010 U.S. Dist. LEXIS 20788* (E.D.N.Y.).

46. *Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 122 (2d Cir. 2006)* (quoting *FTC v. Standard Fin. Mgmt. Corp., 830 F.2d 404,409 (1st Cir. 1987)).*

47. *Stern,* 529 F. Supp. 2d at 420.

48. Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023(CBA), *2010 U.S. Dist. LEXIS 20788,* at *9 (E.D.N.Y. 2010) (quoting *United States v. Amodeo,* 71 F.3d 1044, 1049 (2d Cir. 1995)*).*

49. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1351 (Fed. Cir. 2012).

50. *Nycomed, 2010 U.S. District LEXIS 20788, at *12.*

51. *Paulsen v. Case Corp.*, 168 F.R.D. 285 (C.D. Cal. 1996).

52. FED. R. CIV. P. 26(c)(1).

53. *Id.* at 26(c)(1)(G).

54. *Paulsen v. Case Corp.*, 168 F.R.D. 285, 289 (C.D. Cal. 1996).

55. *Hamilton v. State Farm Mut. Auto. Ins. Co.*, 204 F.R.D. 420, 422 (S.D. Ind. 2001).

56. FED. R. Civ. P. 26, 45;

57. *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MO-1789(JCF), 2009 U.S. Dist. LEXIS 70246, at *30 (S.D.N.Y.).

58. *Massey Coal Servs., Inc. v. Victaulic Co. of Am.*, 249 F.R.D. 477 (S.D.W. Va. 2008).

59. *Cipollone v. liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1987)

60. *Massey Coal Servs., Inc.*, 249 F.R.D. 477.

61. *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1987)

62. *Cipollone*, 785 F.2d at 1121.

63. *Massey Coal Servs., Inc.*, 249 F.R.D. at 482.

64. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1351-52 (Fed. Cir. 2012); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013).

65. FED. R. CIV. P. 45(d)(3)(B)(i).

66. *Insulate America v. Masco Corp.*, 227 F.R.D. 427, 432 (W.D.N.C. 2005)

67. *Dorel Juvenile Grps., Inc. v. Summer Infant, Inc.*, C 06-91 S, 2006 U.S. Dist. LEXIS 77906 (D.R.I. Oct. 11, 2006)

68. FED. R. CIV. P. 45.

69. Merriam Webster, Subpoena, MERRIAM WEBSTER ONLINE, http://www.merriam-webster.com/dictionary/subpoena)(last

visited Nov. 27, 2021). FED. R. CIV. P. 45(d)(3)(B)(i).

70. *In re Fosamax Prods. Liab. Litig.*, No. 1 :06-MO-1789(JFK)(JLF), 2009 U.S. Dist. LEXIS 70246, at *26 (S.D.N.Y. Aug. 4, 2009).

71. *In re Fosamax Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 70246, at *28.

72. *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

73. *United States v. Int'l Bus. Mach. Corp.*, 67 F.R.D. 40, 42 n.1 (S.D.N.Y. 1975)

74. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1368 (Fed. Cir. 2012). Id. at 1362 (Rader, J., dissenting).

75. *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

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Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar

Hannah-Alise Rogers

TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER *MOMENTA V. AMPHASTAR*

Hannah-Alise Rogers[*]

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[*] Hannah-Alise is a native of Atlanta, Georgia, and attends law school at the University of Georgia School of Law. Her primary interests are healthcare finance and regulatory law, and she hopes to begin her practice in Washington, D.C. after graduation. Hannah-Alise would like to thank Professor Joseph Miller and the staff of the *Journal of Intellectual Property Law* for their help in preparing this Note for publication.

I. INTRODUCTION

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs is steadily growing.[1] The pharmaceutical industry is responsible for over three million American jobs, and pharmaceutical companies invest millions of dollars in promoting the research and development of new and generic drugs.[2] In order to retain their competitive advantage, most pharmaceutical drug manufacturers seek patent protection.[3] Manufacturers have learned to think creatively, using a variety of patents—including method, design—and research tool patents—in order to fully protect their lucrative inventions. Congress encourages biomedical research and technological innovation through the patent system.[4] Congress heavily regulates the pharmaceutical industry both directly through status such as the Federal Food, Drug, and Cosmetics Act[5] and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act),[6] and indirectly through regulations promulgated by the Food and Drug Administration (FDA).[7] Several volumes of the Code of Federal Regulations are specifically dedicated to describing what manufacturers must do in order to market a drug in the United States.[8]

Due to recent congressional legislation and judicial decisions, however, generic drug manufacturers have lost some previously afforded patent protections,[9] specifically with respect to their bioequivalency test method patents. For example, the safe harbor provision of the Hatch-Waxman Act allows competing drug manufacturers to "borrow" information within the patents of their competitors so long as they agree to use the patents in furtherance of submitting information to the FDA.[10] Competing generic drug manufacturers, for example, can take bioequivalency tests disclosed in the

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[1] *The U.S. Pharmaceutical Industry*, SELECTUSA.GOV, http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-and-biotech-industries-united-states (last visited Oct. 14, 2014).

[2] *Id.*

[3] *Getting Generic Drugs Q & A*, FEDERAL TRADE COMM'N, http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions (last visited Sept. 30, 2014).

[4] JOSEPH MILLER & LYDIA LOREN, INTELLECTUAL PROPERTY LAW: CASES AND MATERIALS 118 (Ver. 3.1 2013).

[5] Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[6] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[7] 21 C.F.R. § 1 (2013).

[8] *Id.*

[9] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Fed. Cir. 2012); Teva Pharm., USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

[10] 35 U.S.C. § 271(e)(1) (2013).

applications of their competitors and use the tests to manufacturer their own generic drugs. A bioequivalency test is a method of testing a generic drug that proves that it is equivalent to a name brand drug that has already received FDA approval. All generic drug applications must demonstrate bioequivalency, thus the tests are extremely valuable. Unfortunately, bioequivalency testing methods can be very costly and time consuming to develop, so generic manufacturers patent the tests in an effort to protect them from use by competitors. The safe harbor provision has thus thwarted the protection scheme on which generic manufacturers depended.

The Federal Circuit recently expanded the scope of the safe harbor provision in 2012 in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*[11] A majority of the Federal Circuit in *Momenta* held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented bioequivalency testing methods for pre-clinical research and manufacturing without incurring infringement liability.[12] In 2003, Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) to the FDA to market Enoxaparin, a generic version of the name brand drug Lovenox, which is used to prevent blood clots.[13] As a result of submitting the ANDA, Aventis, the manufacturer of Lovenox, sued Amphastar; after several years of expensive patent litigation, the FDA granted Amphastar's ANDA, allowing it to manufacture enoxaparin.[14] In the meantime, however, before the FDA granted Amphastar's ANDA for enoxaparin, Momenta "borrowed" Amphastar's bioequivalency test, which was publicly disclosed in Amphastar's ANDA and used the test to beat Amphastar to the market by more than a year.[15] This one year boost resulting from "borrowing" Amphastar's patent for bioequivalency allowed Momenta a monopoly on the generic market, resulting in profits of over $260 million per quarter.[16]

This Note argues that the Federal Circuit's holding in *Momenta* threatens manufacturers with a devastating loss of previously available patent protection for measuring the bioequivalency of generic drugs. The Note concludes that trade secret law is the best alternative to patent protection until Congress decides to narrow the scope of the Hatch-Waxman Act's safe harbor provision. Due to the high cost of submitting a New Drug Application or an ANDA to

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[11] *Momenta Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).
[12] *Id.* at 1361.
[13] *Id.* at 1351.
[14] *Id.*
[15] *Id.*
[16] *Id.*

the FDA, generic drug manufacturers want to seek protection for their bioequivalency tests so that consumers can reap the benefits of competition. In other words, giving generic manufacturers the ability to protect their bioequivalency tests would incentivize the production of generic drugs, which would in turn benefit consumers. However, in light of *Momenta*, this protection is no longer available through patent law.[17] Additionally, the Federal Circuit's interpretation of Hatch-Waxman's safe harbor provision has frustrated the generic drug manufacturer's ability to protect its research and development investments. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods for bioequivalency from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect bioequivalency tests as trade secrets.

Part II of this Note first describes the FDA's method of regulating generic drugs, including the process of submitting an ANDA, to demonstrate why this process is important to the patent protection which *Momenta* has recently frustrated for manufacturers. This section then explains how some of the information submitted to the FDA in furtherance of the ANDA can be protected through trade secret law instead of through patent law.

Part II next reviews the relevant parts of the Hatch-Waxman Act and specifically focuses on the evolution of the safe harbor provision, codified at 35 U.S.C. § 271(e)(1). Moreover, this Part explores prior United States Supreme Court opinions leading up to *Momenta* which have interpreted the safe harbor provision and demonstrates that the scope of the safe harbor provision has been expanded to such an extent that protection via method patents for bioequivalency tests is no longer available.

Additionally, Part II summarizes the current state of trade secret law and demonstrates how a bioequivalency test could qualify as a trade secret. This part also discusses the four potential threats of disclosure that a bioequivalency test trade secret could face, including FOIA requests, FDA use, and litigation; related threats, including the common law right of public access and discovery requests.

Part III argues that trade secret law is not only available to generic manufacturers but is ultimately a better alternative to protecting bioequivalency tests than patent law. Part III demonstrates how generic manufacturers can overcome threats of disclosure of their trade secrets presentation FOIA requests, FDA use and disclosure, and litigation.

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[17] *Id.* at 1362.

II. BACKGROUND

A. FDA SUBMISSION REQUIREMENTS FOR GENERIC DRUGS

Under the Food, Drug and Cosmetics Act of 1938, Congress delegated to the FDA the power to enact specific regulations concerning requirements for marketing new and generic drugs.[18] A new drug or generic bioequivalent may not be placed on the market without prior FDA approval.[19] The process for gaining FDA approval is quite extensive, so this Note only discusses the most relevant and important requirements relating to generic drugs.

First, in order to gain FDA approval to manufacture a generic drug, the manufacturer must submit an ANDA. The application must be within one of the FDA's delineated categories of acceptable drug products.[20] ANDAs may be submitted for "[d]rug products that are bioequivalent, or the same as a listed [i.e. name brand] drug. For determining the suitability of an [ANDA], the term 'same as' means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use."[21] Within sixty days of receiving an ANDA, the FDA will conduct a preliminary review of the application to determine whether it may be filed.[22] If the filing of an application is permitted, the party can submit it, and the FDA will then either send an approval of the application or deny it within 180 days of submission.[23]

A central requirement for a successful ANDA is that the generic drug must be the bioequivalent of the listed (i.e., name brand) drug.[24] A bioequivalency test is defined as "[i]nformation that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies."[25] In other words, rather than submitting a New Drug Application, a manufacturer who wants to produce a generic version of an already existing drug proves in its ANDA that the generic is the same as the name brand drug; as a result, generic drug manufacturers are not required to demonstrate safety or efficacy of the drug in their ANDA, since these were already demonstrated in the application of the original manufacturer.[26] Bioequivalency tests are thus of critical

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[18] P.L. 75-717, 52 Stat. 1040 (1938).
[19] 21 C.F.R. § 314.105(a) (2013).
[20] *Id.* § 314.92(a).
[21] *Id.* § 314.92(a)(1). For more on the requirements for the acceptable types of drug products, see *id.* §§ 314.92(a)(1), 314.122.
[22] *Id.* § 314.101(a)(1).
[23] *Id.* § 314.100(a).
[24] *Id.* § 314.94(a)(7).
[25] *Id.* § 314.94(7)(i).
[26] *See supra* note 1.

importance to ANDAs, and even the analytical and statistical methods used in determining bioequivalency are subjected to FDA regulation.[27]

In addition, a completed ANDA form must contain the following parts: a table of contents; a basis for submission (meaning the application must refer to a listed drug); the conditions under which the drug can be used; the drug's active ingredients (which must be the same as the active ingredients in the listed drug); the route of administration, strength, and dosage form of the drug (which must be the same as those in the listed drug); bio-equivalence (discussed further below); the labeling and proposed labeling for the drug; the chemistry, manufacturing process, and controls of the drug; any drug samples requested by the FDA; any patent certifications used in the manufacture of the drug; and a statement of financial certification or disclosure.[28] Additionally, "[a] complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval."[29] As discussed in Part III, the FDA may freely use the information that it receives in an ANDA, and the FDA, like other Federal Agencies, has a broad disclosure policy, meaning that the FDA allows the public to obtain Agency information whenever appropriate.[30]

Once a method for determining bioequivalency is established, generic drugs can be quickly and more easily produced because the drug manufacturers can demonstrate that the generic is the same as the listed drug, which has already extensively tested by the FDA. Generic competitors thus have a great incentive to steal these bioequivalency testing methods in order to accelerate the process of submitting an ANDA. Because the process of developing a bioequivalency test can be expensive and time consuming, generic drug manufacturers need assurance that the tests will receive some type of protection in order to incentivize their development.[31] Given the breadth of information, time, and money required to submit an ANDA, generic manufacturers seek patent protection in order to make their investments worthwhile.

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[27] 21 C.F.R. § 314.94(7)(iii); *see also id.* §§ 56.104, 56.105 (providing exceptions to normal IRB requirements).

[28] *Id.* §§ 314.94(a)(1)–(12).

[29] *Id.* § 314.94(7)(i).

[30] *See infra* text accompanying note 162 and discussion that follows.

[31] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Fed. Cir. 2012) (plaintiff patent holder sought enforcement of its method patent for a bioequivalency test); Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.) (involving a similar fact pattern).

B. THE SCOPE OF THE SAFE HARBOR PROVISION OF THE HATCH-WAXMAN ACT

In order to demonstrate the breath of the problem that the Federal Circuit's ruling in *Momenta v. Amphastar* has caused, this section discusses how the FDA's regulations regarding generic drugs intersect with the Hatch-Waxman Act. The relationship between the Hatch-Waxman Act and RDA regulations is critical for understanding why the Federal Circuit's holding in *Momenta* frustrated the usefulness of patent protection for bioequivalency research and development. In order to fully understand the goals and problems of the Hatch-Waxman Act, it is first helpful to review the history which led to the statute's enactment.

Before the Hatch-Waxman Act became effective in September of 1984, there were no statutory provisions to protect pharmaceutical companies from a competitor's allegations of patent infringement when they used another's patented technology to perform pre-approval clinical research.[32] Congress enacted the Act's safe harbor provision "to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement."[33] The Act specifically overruled the Federal Circuit's opinion in *Roche Prods. v. Bolar Pharmaceutical Co.*[34] *Roche* held that a competing drug manufacturer infringes by using a competitor's patent for pre-clinical research because borrowing patented information for research purposes falls outside of the scope of the experimental use rule,[35] which "ends with an actual reduction to practice."[36] The Federal Circuit declared, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of scientific inquiry, when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[37] This precedent left no protection to pharmaceutical companies alleged to infringe by competitors when they used another's patented technology to perform FDA pre-approved clinical research.

The safe harbor provision of the Hatch-Waxman Act,[38] now clarifies:

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[32] Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

[33] H.R. REP. NO. 98-857, pt. 1, at 45 (1984) (quoting Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1362 (Rader, C.J., dissenting)).

[34] *Id.* pt. 2, at 27.

[35] *Roche Prods.*, 733 F.2d at 863. The experimental use rule is "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement [and] is not an infringement of the rights of the patentee." *Id.* at 862 (internal quotations omitted) (internal citations omitted).

[36] Nordberg Inc. v. Telsmith, Inc., 881 F. Supp. 1252, 1285 (E.D. Wis. 1995) (internal quotation marks omitted).

[37] *Roche Prods.*, 733 F.2d at 863.

[38] H.R. REP. NO. 98-857, pt. 2, at 27 (1984).

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[39]

Since the passage of the statute, the Supreme Court has interpreted its meaning fairly expansively.[40] This Note will next briefly summarize the Supreme Court's interpretations of the safe harbor provision, leading to the Federal Circuit's most recent expansion in *Momenta*.

The controversy over the scope of the safe harbor provision began early in the statute's history; the Supreme Court first interpreted the safe harbor provision only six years after it was enacted in *Eli Lilly & Co. v. Medtronic, Inc.*[41] *Eli Lilly* concerned whether the safe harbor provision applied to patented medical devices in addition to prescription drugs.[42] The Supreme Court broadened the application of the statute to not only to drug patents, but also to medical devices.[43] In writing for the majority, Justice Scalia reached this expansive holding by citing the Act's purpose according to the legislative history "to respond to two unintended distortions on the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval."[44] According to the majority, Congress designed the safe harbor provision to prevent the patentee from having an extended monopoly on the market simply by virtue of the amount of time it takes another company to produce a bioequivalent drug.[45] The majority additionally argued that the statute "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."[46]

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[39] 35 U.S.C. § 271(e)(1) (2012).

[40] *See* 496 U.S. at 665 (finding no infringement under § 271(e)(1) in the case of a patented medical device); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (holding that the use of a patented compound was protected by § 271(e)(1) as long as it was reasonable to believe that the compound tested could be submitted to the FDA at some later time and the experiments for which the compound was used would produce information relevant to an application).

[41] 496 U.S. 661.

[42] *Id.* at 663.

[43] *Id.* at 665.

[44] *Id.* at 669.

[45] *Id.* at 672–73.

[46] *Id.* at 671.

However, Justices Kennedy and White dissented, arguing the safe harbor provision should not apply to anything beyond obtaining market approval for a drug, and that the statute should not apply to "all" products regulated by the FDA.[47] Justice Kennedy explained that the testing of medical devices should not be protected by the safe harbor because Congress could not have intended for such an extraordinary meaning of the specific language in the statute.[48]

In 2005, the Supreme Court again interpreted the scope of the safe harbor provision in *Merck KGaA v. Integra Life Sciences I, Ltd.*[49] *Merck* posed the question of whether a manufacturer could use patented inventions during preclinical research under the immunity of the safe harbor provision when the results were not actually submitted to the FDA.[50] Justice Scalia delivered a short, and probably too informal, unanimous opinion, holding that the safe harbor provision's exception to infringement:

> [N]ecessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.[51]

Thus, the *Merck* Court again widened the scope of the safe harbor provision.

Following suit, the Federal Circuit further expanded the safe harbor provision of the Hatch-Waxman Act in *Momenta v. Amphastar*. The issue in *Momenta* was whether the defendant generic manufacturer lawfully used the plaintiff competitor's patented test for bioequivalency to test its own form of the generic drug Enoxaparin.[52] Defendant Amphastar argued that it did not infringe because it used the plaintiff's patent to test their own version of the generic drug Enoxaparin and submitted these test results to the FDA, therefore falling within the scope of the safe harbor.[53] The court agreed with the defendant that its use of momenta's bioequivalency test for Enoxaparin was "solely for uses reasonably related to the development and submission of information under a Federal law"; and thus was permissible under the safe

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[47] *Id.* at 680 (Kennedy, J., dissenting).
[48] *Id.*
[49] 545 U.S. 193 (2005).
[50] *Id.* at 195.
[51] *Id.* at 202.
[52] Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1350 (Fed. Cir. 2012).
[53] *Id.* at 1352–53.

harbor provision.[54] The majority relied primarily on the text of the statute to support its position, arguing specifically that the phrase 'under a federal law' "extend[ed] beyond just the 'most barebones information' required by the FDA, and instead encompass[ed] all 'materials the FDA demands in the regulatory process.' "[55] Chief Judge Rader, however, relied on congressional purpose to dictate a different result.[56]

In a strong dissent, Chief Judge Rader argued that Amphastar's actions exceeded the scope of the safe harbor provision because Amphastar used Momenta's patent for more than the mere submission of information to the FDA.[57] In his view, "Amphastar stepped in and took Momenta's patented invention without permission and used it to manufacture each commercial batch [of Enoxaparin] it sells on the market."[58] Additionally, the fact that Amphastar could only compete with Momenta by using its patent strengthened Chief Judge Rader's conclusion that the safe harbor provision should be more limited in scope.[59] In reaching this conclusion, Chief Judge Rader relied on legislative history to support his argument that Congress did not intend to give manufacturers the right to use another's patented process to place a competing drug on the market,[60] and criticized the majority for totally ignoring it.[61] The safe harbor provision, he noted, was a congressional compromise because of its limited scope in time, quantity, and type.[62] The time period covered by the safe harbor was only for pre-market approval; in other words, after the FDA approves the drug, the safe harbor provision does not protect further marketing activities.[63] In terms of the safe harbor provision's limitations on quantity and type, Chief Judge Rader explained that the statute "only applies to experimentation—and therefore would have limited impact on the patentee's exclusivity during the life of the patent."[64] In all, Chief Judge Rader concluded that the safe harbor provision did not protect Amphastar from its use of

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[54] *Id.* at 1353 (quoting 35 U.S.C. § 271(e)(1)).

[55] *Id.* at 1356 (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1683 (2012)).

[56] *Id.* at 1362 (Rader, J., dissenting).

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.* at 1362–63 (quoting H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

[61] *Id.* at 1366.

[62] *Id.* at 1365 (citing *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcom. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association)).

[63] *Id.*

[64] *Id.* at 1365–66 (citing H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

Momenta's patented bioequivalency test because Amphastar continued to use the test after it gained FDA approval, thus destroying Momenta's right to exclude.[65] As he lamented, "This result will render worthless manufacturing test method patents."[66]

Chief Judge Rader reached this fear that test method patents would no longer offer protection to patent holders by considering the implications of the majority's holding.[67] He argued that the majority of the Supreme Court and the Federal Circuit have interpreted the safe harbor provision so broadly as to allow competitors to use patented testing methods not just for pre-clinical research but also for manufacturing.[68] Patents exist to define the exclusion rights of their holders,[69] but the exclusion rights in this scenario have been all but snatched away, presenting a problem for generic drug manufacturers who spend millions of dollars developing tests to determine bioequivalency, and then seek to protect these tests from the hungry eyes of their competitors.

C. A BRIEF OVERVIEW OF PATENT PROTECTION

In order to understand what generic manufacturers have lost by their inability to protect their bioequivalency tests via patent law, this section briefly reviews the protection that manufacturers would receive from patents absent the *Momenta v. Amphastar* holding. Patent law's origin rests in the United States Constitution,[70] which has been codified to protect "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" that is invented or discovered.[71] In order to receive patent protection for an invention falling within one of these eligible categories, one must disclose his or her invention to the Patent Trademark Office (PTO)[72] and meet the other statutory requirements of novelty and non-obviousness.[73] Patent law's scheme of protection of information via this disclosure process could be seen as the opposite of trade secret protection, which attempts to retain the value of information by protecting it against public disclosure.[74]

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65 *Id.* at 1367.
66 *Id.* at 1362.
67 *Id.*
68 *Id.* at 1361. *See also* Merck KGaA v. Integra Life Sciences I, Ltd., 545 U.S. 1953 (2005).
69 *Id.*
70 U.S. CONST. art. 1, § 8, cl. 8.
71 35 U.S.C. § 101 (2006).
72 MILLER & LOREN, *supra* note 4, at 117.
73 35 U.S.C. §§ 102–103.
74 MILLER & LOREN, *supra* note 4, at 27.

Assuming that all the requirements for a valid patent are met,[75] the patentee receives protection for his or her invention for a period of twenty years.[76] During this time, the patentee holds an exclusive right to use the patented process, machine, manufacture, or composition of matter.[77] In the context of bioequivalency testing methods of pharmaceutical drugs testing, the applicable patent eligible category is "process." Therefore, this Note proceeds referring solely to "process" patents, also known as method patents.

If a patentee discovers that another entity is performing its patented process, the patentee can sue this competitor for infringement.[78] If a court finds that the competitor infringes, the patentee is entitled to monetary damages and/or an injunction.[79] Overall, patent protection is bent towards protection for an invention via disclosure of that invention,[80] unlike trade secret protection, discussed below, which affords protection for inventions by keeping them a secret.[81]

D. A LOOK AT THE STATE OF TRADE SECRET LAW AND THE POTENTIAL THREATS OF DISCLOSURE

A generic manufacturer need not register its bioequivalency test as a trade secret, but in order to qualify for trade secret protection, a bioequivalency test must meet the legal definition of a "trade secret."[82] This part examines several common definitions of "trade secret," which will be used in Part III to demonstrate how a bioequivalency test fits within the scope of protectability. This section also briefly introduces the ways in which a bioequivalency test protected by trade secret law can be disclosed, including through a FOIA request, FDA use, discovery requests, and the common law right of public access.

Although trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA),[83] was created to make state trade secret law more homogenous and has been adopted by all but three states.[84] The

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[75] For more information on the requirements for a valid patent, see *id.* at 129–54. *See also* 35 U.S.C. §§ 101–103, 112.
[76] 35 U.S.C. § 187.
[77] *Id.* § 254.
[78] *See id.* § 255.
[79] *Id.* §§ 277–278.
[80] *Id.* § 118.
[81] *Id.* § 27.
[82] MILLER & LOREN, *supra* note 4, at 27.
[83] Unif. Trade Secrets Act (1979) (amended 1985).
[84] MILLER & LOREN, *supra* note 4, at 28.

following discussion refers to the UTSA as adopted by New Jersey, a state home to a large percentage of the United States' drug manufacturers.[85]

The New Jersey UTSA outlines the definition of a 'trade secret' and the circumstances under which a trade secret can be misappropriated:

> "[T]rade secret" means information, held by one or more people, without regard to form, including a formula . . . method . . . technique . . . or process that: (1) derives independent economic value . . . from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[86]

The UTSA thus provides direction to generic drug manufacturers seeking to protect their bioequivalency testing methods via trade secret law. However, each manufacturer should look at the specific adoption of the UTSA in their state in order to fully understand the scope of the trade secret protection offered.[87]

In addition to the UTSA, the FDA also promulgates rules and regulations regarding trade secrets, so is important for generic manufacturers to keep the FDA's definition of "trade secret" in mind when submitting their ANDAs.[88] Because the FDA receives a great deal of information from generic drug manufacturers, disclosure of this information to the public is of high importance to a manufacturer seeking protection. The FDA's provisions regarding the protection of submitted information strikingly states that "[t]he [FDA] will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information."[89] It continues: "Except where specifically exempt pursuant to the

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[85] *Pharmaceuticals*, STATE OF NEW JERSEY BUSINESS PORTAL, http://www.nj.gov/njbusiness/industry/pharmaceutical/ (last visited Sept. 30, 2014).

[86] N.J. STAT. ANN. § 56:15-2 (West 2012).

[87] With the exception of Massachusetts and New York, each state has adopted some form of the UTSA. While the laws are similar, it is helpful to refer to a state's specific version of the UTSA as a measure of precaution. For a full list of each state's UTSA law, see *Trade Secrets Laws: State Law*, ORRICK, HERRINGTON & SUITCLIFF, LLP, http://blogs.orrick.com/trade-secrets-watch/trad e-secrets-laws/ (last visited Nov. 13, 2014).

[88] *See* 21 C.F.R. § 20.61 (2013).

[89] *Id.* § 20.20(a).

provisions of this part, all FDA records shall be made available for public disclosure."[90]

Due to the FDA's proclivity towards disclosure of information, the FDA's definition of "trade secret" is essential for the protection of information.[91] Courts have grappled with how expansively to construe the definition,[92] which reads:

> A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.[93]

Because requests for information made under the FOIA are a common way in which information known by the FDA can be disclosed, generic manufacturers will likely want to know whether trade secrets that are submitted to the FDA as a part of an ANDA could be disclosed by a FOIA request.[94] The Freedom of Information Act first became effective in 1967, and controls the public disclosure of previously unreleased information from federal agencies.[95] The primary purpose of the FOIA is to enable the public to access government records in order to gain a greater understanding of the government.[96] FOIA disclosures include everything from substantive and procedural rules regarding disclosure of information,[97] administrative case law reporting,[98] and statements of policy and agency interpretations.[99] Perhaps the most controversial part of FOIA is found in section 3:

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[90] *Id.* § 20.20(b).

[91] *Id.* § 20.61(a) ("The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.").

[92] *See, e.g.*, Public Citizen Health Research Group v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[93] 21 C.F.R. § 20.61(a).

[94] Pub. L. No. 89-487, 80 Stat. 250 (1967) (codified at 5 U.S.C. § 552).

[95] *What is FOIA*, FOIA.GOV, http://www.foia.gov/about.html (last visited Nov. 14, 2014).

[96] *Id.*

[97] 5 U.S.C. § 552(a)(1)(A)–(E) (2012).

[98] *Id.* § 552(a)(2)(A).

[99] *Id.* § 552(a)(2)(B).

> Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person.[100]

The agency must also perform a reasonable search to find the information[101] and must provide the information in the format requested.[102] Like many other federal agencies, the FDA has its own Freedom of Information A
ct Office, called the Food and Drug Administration Division of Freedom of Information,[103] wherein a person who is seeking information from the FDA must submit a request.[104]

Although the FOIA attempts to make as much agency information available to the public as possible, there are some exceptions to what information a petitioner can receive. For example, agencies may withhold information that is labeled confidential for the purposes of national security by an executive order,[105] information that is solely related to agency personnel rules,[106] and information that is "exempted from disclosure by statute."[107] For information to be exempt by a specific statute, the statute must be clear as to what type of information may be withheld[108] and must cite to the FOIA, in limited circumstances.[109] Finally, exceptions to FOIA also exist for "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"[110] agency memorandums,[111] and medical/personnel files.[112] Although an exemption exists

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100 *Id.* § 552(a)(3) (emphasis added).
101 *Id.* § 552(a)(3)(C).
102 *Id.* § 552(a)(3)(B).
103 21 C.F.R. § 20.30(a) (2013).
104 *Id.* § 20.30(b).
105 5 U.S.C. § 552(b)(1)(A) (2012).
106 *Id.* § 552(b)(2).
107 *Id.* § 552(b)(3) (to be exempted, the statute in question must "(i) require[] that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establish[] particular criteria for withholding or refer[] to particular types of matters to be withheld; and (B) . . . specifically cite [] to this paragraph." (*id.* § 552(b)(3)(A)(i)–(ii); (B))).
108 *Id.* § 552(b)(3)(A)(i)–(ii).
109 *Id.* § 552(b)(3)(B).
110 *Id.* § 552(b)(4).
111 *Id.* § 552(b)(5).
112 *Id.* § 552(b)(6).

for trade secrets, manufacturers will have concerns that their bioequivalency tests, which are worth millions of dollars, may not fit within the scope of protection.

Hypothetically, if a generic manufacturer were to choose to protect its bioequivalency test via trade secret law, a competitor could try to access the test information by submitting a FOIA request for it. Anyone who wishes to request information from the FDA must submit a FOIA request in writing to the FDA's headquarters in Maryland.[113] The writing must reasonably set forth the information being requested.[114] So long as the writing reasonably details the information sought, "[e]very reasonable effort shall be made by the [FDA] to assist in the identification and location of the records sought."[115] The person submitting the request must also pay a fee, the amount of which is determined by the type of information requested.[116] If the confidentiality of requested information is uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information.[117]

If the FDA rejects a request for information, "the decision constitutes final agency action that is subject to judicial review."[118] The person requesting the information will be notified of the FDA's rejection and will then have five days after receipt of notification to file a suit in a United States District Court.[119] When trade secret information is requested and disclosure is denied,[120] the FDA will inform the person who submitted the record that he or she must come and defend the record's confidentiality in court.[121] The statute reads, "If the affected person fails to intervene to defend the exempt status of the records . . . the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure."[122] Thus, the FDA expects the person who submits information classified as a trade secret to defend this status if it is challenged. While defending the trade secret status is not mandatory under the statute, it factors into the FDA's decision of whether or not to disclose the information.[123]

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113 21 C.F.R. § 20.40(a) (2013).
114 *Id.* § 20.40(b).
115 *Id.* § 20.40(b)(2).
116 *See id.* § 20.45(a)(1)–(3).
117 *Id.* § 20.47.
118 *Id.* § 20.48.
119 *Id.*
120 Disclosures are denied under 21 C.F.R. § 20.61.
121 21 C.F.R. § 20.55.
122 *Id.*
123 *Id.*

Finally, even if a generic manufacturer meets the FDA's definition of trade secret when submitting an ANDA and the FDA's disclosure of the information via a FOIA request is limited, both the common law right of public access[124] and discovery requests[125] pose additional threats for generic manufacturers who wish to protect their trade secrets. The common law right of public access can arise during or after a lawsuit and poses a threat to generic manufacturers' ability to protect bioequivalency tests, as courts strive to maintain open records of judicial proceedings. The Second Circuit explains in *Nycomed US, Inc. v. Glenmark Generics, Inc.*, that the right of public access allows open access to judicial documents to provide information to the public in hopes of making the courts appear more legitimate.[126] For the purposes of this Note, the definition of "judicial documents" is particularly relevant because as the Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, judicial documents are presumed to be open to public access, as described in Part III.[127]

In *Stern v. Cosby*, the Second Circuit additionally developed a three-part test to determine whether a judicial document is subject to the common law right of public disclosure.[128] "First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it."[129] Altogether the right of public access threatens disclosure of trade secrets. However, a generic manufacturer can successfully argue that bioequivalency tests disclosed in ANDAs should not be subject to the common law right of public access.[130]

Likewise, discovery requests also pose a threat to generic manufacturers who could protect their bioequivalency tests as trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery,[131] but Rules 26 and 45 can help generic

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[124] *See, e.g.*, Stern v. Cosby, 529 F. Supp. 2d 417 (S.D.N.Y. 2007).

[125] *See, e.g.*, Massey Coal Services, Inc. v. Victaulic Co. of Am., 249 F.R.D. 477 (S.D. W. Va. 2008).

[126] Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023 (CBA), 2010.

[127] 435 F.3d 110, 122 (2d Cir. 2006) (quoting FTC v. Standard Fin. Mgmt. Corp., 830 F.2d 404, 409 (1st Cir. 1987)) ("[R]elevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings become documents to which the presumption of public access applies.").

[128] Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007).

[129] *Id.* (quoted in Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.) (internal quotation marks omitted)).

[130] *See infra* notes 196–208.

[131] *See generally* Paulsen v. Case Corp., 168 F.R.D. 285 (C.D. Cal. 1996).

manufacturers to protect their bioequivalency test trade secrets from disclosure during litigation. Rule 26 provides a scenario in which a party may receive a protective order from the court in order to guard against the disclosure of a trade secret[132]: "The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action."[133] Then, the rule states, "the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" by several following methods.[134] One of the following ways to protect a party includes: "requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way."[135] Because any relevant evidence will lend a presumption of admissibility, the party seeking protection has the burden of proof that the information should not be disclosed.[136] Thus, although there is no per se protection of trade secrets in the Federal Rules of Civil Procedure,[137] generic manufacturers could use Rule 26 and case law relating to discovery and the common law right of public access to argue that their bioequivalency tests protected as trade secrets should not be disclosed.

Like Rule 26, Rule 45 also helps ensure that trade secrets are not wrongfully disclosed during discovery by protecting trade secrets from subpoenas. A subpoena is an order from a government agency, usually a court, which compels a witness to testify or produce evidence.[138] In relevant part, Rule 45 states, "To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information. . . ."[139] Subsequent case law has stated that when a court is deciding whether to quash a subpoena which seeks information marked as a trade secret, "a court must evaluate all the circumstances and balance, *inter alia*, the requesting party's need for the information and the potential prejudice imposed on the requested party."[140] Furthermore, the factors to be balanced include "the relevance of the discovery

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132 FED. R. CIV. P. 26(c)(1).
133 *Id.*
134 *Id.*
135 *Id.* at 26(c)(1)(G).
136 *In re* Fosamax Prods. Liab. Litig., 2009 U.S. Dist. LEXIS 70246, at *31 (S.D.N.Y.).
137 *See* Paulsen v. Case Corp., 168 F.R.D. 285, 289 (C.D. Cal. 1996).
138 Merriam Webster, *Subpoena*, MERRIAM WEBSTER ONLINE, http://www.merriam-webster.com/dictionary/subpoena (last visited Sept. 30, 2014).
139 FED. R. CIV. P. 45(d)(3)(B)(i).
140 Insulate America v. Masco Corp., 227 F.R.D. 427, 432 (W.D.N.C. 2005) (citations omitted).

sought, the requesting party's need, and the potential hardship to the party subject to the subpoena."[141]

Altogether, the numerous rules that govern the FDA's submission of information, FOIA requests, the FDA's use, the common law right of public access, and discovery requests could each pose a threat to manufacturers who wish to protect their bioequivalency tests via trade secret law. Nevertheless, there are various situations in which a competing drug manufacturer could attempt to access a bioequivalency test protected by trade secret law, as next explained in Part III. These situations include disclosure requests from third parties,[142] threats of disclosure or use by the FDA,[143] and the threat of disclosure during litigation through the assertion of common law right of public access or a discovery request.[144] A generic manufacturer seeking to protect its bioequivalency test via trade secret law should pay close attention to the way courts define the scope of trade secret and the various methods that competitors can use to seek disclosure of trade secret information.

III. ANALYSIS

Given *Momenta*'s holding that the safe harbor provision of the Hatch-Waxman Act encompasses a drug manufacturer's use of another's bioequivalency testing methods for pre-clinical research and manufacturing, patent law offers little to no protection for generic manufacturers who wish to protect their bioequivalency tests from appropriation by competitors.[145] Because FDA regulations of ANDAs are complex and require each manufacturer to make a specific showing of how it meets the requirements to legally manufacture a drug, as discussed above, the FDA requires generic drug manufacturers to disclose their bioequivalency testing methods to ensure that a drug in production is both safe and effective.[146] Due to the extensive information required by the FDA, ANDAs are therefore expensive to produce. Moreover, since bioequivalency tests can be difficult, time consuming, and expensive to develop, generic manufacturers often use patent protection to

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[141] Dorel Juvenile Grps., Inc. v. Summer Infant, Inc., C 06-91 S, 2006 U.S. Dist. LEXIS 77906 (D.R.I. Oct. 11, 2006) (quoting Heat & Control, Inc. v. Hester Indus., Inc., 785 F.2d 1017, 1024 (Fed. Cir. 1986)).

[142] *See* Public Citizen Health Research Group v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[143] *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984) (involving a similar situation in the Environmental Protection Agency).

[144] *See* Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (S.D.N.Y.).

[145] Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (Rader, J., dissenting).

[146] *See supra* notes 17–25 and accompanying text.

make investment in bioequivalency testing methods worthwhile. However, after the *Momenta* holding, adequate patent protection of bioequivalency tests has been lost, leaving generic manufacturers little incentive to invest in their development. Nevertheless, trade secret law endures to protect generic drug manufacturers' bioequivalency tests from appropriation by competitors. This Note argues that trade secret is in fact the best and most natural method for protecting bioequivalency tests after *Momenta*, and therefore seeks to advise generic drug manufacturers of the potential hurdles to overcome in gaining such protection.

This section first discusses the scope of the definition of trade secret in various contexts, keeping in mind that competitors who seek the information will try to attack the definitions of both the UTSA and the FDA. Next, this section explores the different ways for generic manufacturers to overcome potential threats of misappropriation, in particular by jumping three different anticipated hurdles to trade secret protection. These hurdles are: a FOIA request made by a third party, potential use and disclosure of protected information via FDA regulations, and disclosure during litigation via the common law right of public access and the discovery process. Finally, this section argues how each of these potential threats to protecting bioequivalency tests can be avoided.

A. THE SCOPE OF THE DEFINITION OF "TRADE SECRET"

Before seeking trade secret protection for a bioequivalency testing method, it is important to look at the exact definition of "trade secret" in order to understand exactly what can be protected. As was explored above, there are different working definitions of what constitutes a trade secret, and each is important different contexts.[147] Generic manufacturers seeking to protect their bioequivalency tests via trade secret law should this to make sure to distinguish these definitions from each other and understand when each definition applies. Two of the relevant definitions of trade secret are the UTSA definition[148] and the FDA's definition.[149]

A bioequivalency testing method would be considered a 'trade secret' for the purposes of both the UTSA and the FDA's definitions. The UTSA has a broad definition of "trade secret," including formulas, methods, techniques, or processes.[150] Similarly the FDA, defines a trade secret as, "[A]ny commercial

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[147] *See supra* notes 77–87 and accompanying text.
[148] *See supra* note 92.
[149] 21 C.F.R. § 20.61 (2013). *See also supra* note 93.
[150] *See supra* note 92.

valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[151] A bioequivalency test would easily classify as a trade secret under either of these definitions as a formula is used for the purposes of demonstrating that a generic drug is the bioequivalent of, or the same as, the name brand.[152] Since bioequivalency testing methods should meet either the UTSA or FDA definition of trade secret, generic manufacturers do retain an incentive for economic investment in their development, despite the inadequacy of patent protection to do the same after the *Momenta* court's holding.

B. THE THREAT OF DISCLOSURE

Once a generic manufacturer decides to protect bioequivalency test as a trade secret, there are three potential ways in which a generic drug manufacturer's trade secret could be disclosed: first, through a FOIA request; second, through use by the FDA itself; and third, through an assertion of the common law right of public access during the discovery process of litigation.

1. Overcoming the Threat of Disclosure Via a FOIA Request. The D.C. Circuit's discussion of the scope of trade secret protection in the FOIA context in *Public Citizen Health Research Group v. Food & Drug Administration* demonstrates that this scope is broad enough to protect bioequivalency tests.[153] In *Public Citizen Health*, the plaintiff consumer advocacy group sought information from the FDA regarding the safety and effectiveness of an intraocular lens that had been on the market for several years.[154] The manufacturer of the intraocular lenses submitted clinical test results to the FDA, and the manufacturer objected to the disclosure of these results to the petitioner, who had made a FOIA request for them.[155] The court was asked to determine whether the requested records were "immune from disclosure under Exemptions 3 and 4 of the FOIA."[156] As the court explained, "[t]hese exemptions allow the court to withhold, respectively, (1) records that are 'specifically exempted from disclosure by statute' if the relevant statute satisfies one of two limiting conditions and (2) 'trade secrets and

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[151] 21 C.F.R. § 20.61.

[152] *See* Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1350 (Fed. Cir. 2012) (discussing the "sufficient information [needed] to establish that the generic drug has the same active ingredients as the reference drug").

[153] Public Citizen Health Research Grp. v. Food & Drug Admin., 704 F.2d 1280 (D.C. Cir. 1983).

[154] *Id.* at 1283.

[155] *Id.*

[156] *Id.* at 1282.

commercial or financial information obtained from a person and privileged or confidential."[157] In affirming in part and reversing in part, the D.C. Circuit held that the district court "erred in its application of Exemption 3 and adopted an overly broad construction of the term 'trade secrets' in Exemption 4"; therefore, the court partially granted the petitioner's request for the drug manufacturer's clinical test results.[158]

The court's discussion of Exemption 4, and more specifically whether "the requested documents constitute 'trade secrets' [and are therefore] exempt from disclosure"[159] illustrates that manufacturers can shield bioequivalency tests from third parties urging disclosure through a FOIA request by protecting them as trade secrets. After evaluating several different definitions of "trade secrets" at common law, and finding that the Restatement of Torts's expansive definition[160] "would classify virtually all undisclosed health and safety testing data as trade secrets,"[161] the court settled on a more restrictive definition to adopt in FOIA cases.[162] "Defined in its narrower common law sense," a trade secret is "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation of substantial effort."[163] In arguing that this is the best definition of trade secret, the court stated that it "incorporates a direct relationship between the information at issue and the productive process."[164]

Although the court in *Public Citizen Health* chose the more restrictive definition of trade secret, believing that it "hews more closely to language and legislative intent of FOIA than does the *Restatement* approach,"[165] this definition can still be used to protect bioequivalency testing methods. A bioequivalency testing method should qualify as a trade secret because it is "a commercially

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157 *Id.*; *see also* 5 U.S.C. § 522(b)(3), (4).

158 *Public Citizen Health*, 704 F.2d at 1282.

159 *Id.* at 1286; *see also* 5 U.S.C. § 522(b)(4).

160 RESTATEMENT OF TORTS § 757 cmt. b (1939) ("A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."). The definition of 'trade secret' as specified in the Restatement has been adopted by other courts. *See, e.g.*, Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

161 *Public Citizen Health*, 704 F.2d at 1286 (quoting Thomas McGarity & Sidney Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 861 (1980)).

162 *Id.* at 1286–87.

163 *Id.* at 1288.

164 *Id.*

165 *Id.* at 1289.

valuable . . . formula . . . that is used for the making of trade commodities" i.e., a prescription drug, that is the "product of either innovation or substantial effort."[166] There is no doubt that a bioequivalency test would be considered "commercially valuable"; the competing generic manufacturer in *Momenta*, for example, was able to make over $260 million per quarter after using the patent holder's bioequivalency test.[167] Furthermore, a bioequivalency test certainly qualifies as a formula, as it is used for the making of pharmaceutical drugs, which also constitute "trade commodities." There is also a direct relationship between the bioequivalency testing methods and the productive process of manufacturing drugs, unlike the information requested in *Public Citizen Health*.[168] Thus, even under the more restrictive definition of 'trade secret' as used by the D.C. Circuit and some other courts in determining the possibility of disclosure via a FOIA request, a generic manufacturer should be able to protect bioequivalency tests as trade secrets and will be immune from disclosure under Exemption 4 of FOIA.[169]

2. Overcoming Threats of Disclosure Via the FDA's Use and Disclosure of Trade Secrets. In addition to FOIA requests, competitors could potentially gain access to bioequivalency tests protected by trade secret law through the FDA's own use and disclosure of the protected information. While it is true that bioequivalency test trade secrets would have to be disclosed to the FDA in order to submit an ANDA, generic manufacturers should be assured that the FDA can only disclose protected information to third parties under limited circumstances.[170]

The Supreme Court addressed the question of when an agency may use and disclose information that is freely submitted by a manufacturer seeking agency approval to produce a product in *Ruckelshaus v. Monsanto*,[171] whose reasoning can be applied to bioequivalency tests to demonstrate that the scope of trade secret protection is broad enough to prevent the FDA from disclosing the information. The issue in the case was whether a pesticide manufacturer who submitted an application for market approval of its pesticide to the Environmental Protection Agency (EPA) could claim trade secret protection

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166 *Id.*

167 Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351 (Fed. Cir. 2012).

168 *See* 704 F.2d at 1290 ("[W]e conclude that [the records at issue] are not protected under the first prong of Exception 4. The relationship of the requested information to the productive process is tangential at best . . . .").

169 5 U.S.C. § 522(b)(4).

170 *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

171 *Id.* at 990.

for health and safety information submitted as part of the application.[172] Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which gave the EPA the authority to regulate the sale of pesticides.[173] In order to market a pesticide in the United States, a manufacturer must gain EPA approval,[174] which parallels the requirement that a generic manufacturer must have FDA approval in order to market a generic drug.

Monsanto, a company that developed and manufactured pesticides, submitted an application to the EPA for approval to market a new chemical.[175] Throughout the application process, Monsanto took special care to protect health and safety data that they used to test the chemical.[176] The company spent approximately $23.6 million in order to generate this information, and did not want the EPA to use it to test other chemicals.[177] Under the FIFRA statute, however, the EPA was allowed to use information submitted for the registration of a pesticide to evaluate subsequent applications, and the statute also allowed the EPA to publicly disclose some of the submitted information.[178] The statute was silent with regard to the disclosure of health and safety information, which the manufacturer was seeking to protect.[179] The stakes of the case were raised because like developing and marketing a generic drug,[180] manufacturing a pesticide requires expenditures of between five and fifteen million dollars annually over several years.[181] When the EPA tried to use and disclose Monsanto's health and safety information, the company sued, claiming that the EPA's use of its health and safety data constituted a taking and was prohibited under the Takings Clause of the Fifth Amendment.[182]

The Supreme Court asked whether Monsanto had a property interest in the health and safety data, and if it did, whether the EPA's use of the data

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[172] *Id.* at 998.
[173] 61 Stat. 163 (1947), *codified at* 7 U.S.C. §§ 136–136y (2012).
[174] *Ruckelshaus*, 467 U.S. at 991.
[175] *Id.* at 997–98.
[176] *Id.* at 998.
[177] *Id.*
[178] *Id.* at 990.
[179] *Id.* at 991.
[180] Although the cost of developing and manufacturing a generic drug is only about 15% of the price of developing and manufacturing a new, brand name drug (Facts about Generic Drugs, U.S. Food & Drug Admin., http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.html (last updated Sept. 19, 2012)), manufacturing a generic can still cost between $120–$150 million (*ABC News, Bitter Medicine: Pills, Profits and the Public Health*, ABC TELEVISION BROAD., May 29, 2002, LEXIS, News Library, Transcripts File).
[181] *Ruckelshaus*, 467 U.S. at 998.
[182] *Id.* at 1001; *see also* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation.").

constituted a taking.[183] Because Monsanto asserted that the data was a trade secret, the Court chose the Restatement of Torts' definition of 'trade secret' for the purposes of deciding the case.[184] According to the Restatement, a trade secret is "any . . . compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."[185] The Court found that Monsanto did have a property right protectable by the Fifth Amendment in the data.[186] However, the Court also ruled that, "[A]s long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."[187] In other words, because Monsanto was on notice during some of the relevant statutory period that the EPA could use the information to evaluate other chemicals and could subject it to public disclosure, the EPA's use of the information could not constitute a taking for the purposes of the Fifth Amendment. The Court further noted that some of the EPA's disclosure of health and safety information constituted a taking,[188] because Monsanto classified the submitted information as a trade secret, which, for a certain period before the statute was amended, was permitted.[189]

Ruckelshaus offers a lesson to generic drug manufacturers about the limits of the protection offered by trade secret law for their bioequivalency tests. So long as a bioequivalency test meets the appropriate requirements for a trade secret under the Restatement of Torts, a manufacturer has a property interest in the test.[190] This is important because if the test constitutes property, then some immunity against disclosure would apply, and the FDA will not have freedom to disclose the information to whomever asks. However, the holding of *Ruckelshaus* indicates that this exclusion right is not unlimited and that courts would likely be unsympathetic to a generic manufacturer who submitted information to the FDA knowing that the FDA was able to use and disclose certain information.[191] Thus, it is important for generic manufacturers to take precautions demonstrating the value of a bioequivalency test and its utmost

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183 *Ruckelshaus*, 467 U.S. at 1000.
184 *Id.* at 1001.
185 *Id.* (quoting RESTATEMENT OF TORTS § 757 cmt. b).
186 *Id.* at 1003–04.
187 *Id.* at 1007.
188 *Id.* at 1010.
189 *Id.* at 1011.
190 *Id.* at 1003–04.
191 *See id.* at 1007.

importance to the process of manufacturing a generic drug, as did the petitioner in *Ruckelshaus* with the health and safety information pertaining to its pesticide.

Section 20 of the Code of Federal Regulations is particularly instructive as to the FDA's rights to information submitted to it by generic drug manufacturers.[192] The FDA's policy is to make the fullest disclosure of information possible, except when the information falls into a protected category, one of which is a trade secret.[193] For this reason, it is important that drug manufacturers classify bioequivalency tests as trade secrets from the time of their first application for FDA approval. Furthermore, the court will often ascertain the actual value of submitted information by looking at the submitter's own efforts to protect it,[194] so generic manufacturers should take measures to protect the submitted information. For example, in *Ruckelshaus*, the Court noted, "Monsanto has instituted stringent security measures to ensure the secrecy of the data."[195] Thus, if generic manufacturers take steps to protect their bioequivalency tests from disclosure before the information is submitted to the FDA, this evidence of the tests' value would cut in favor of the manufacturer were the FDA to consider disclosure. While the *Ruckelshaus* Court noted that "the Trade Secrets Act is not a guarantee of confidentiality to submitters of data,"[196] classifying information as a trade secret *before* submitting the information to the FDA can offer the submitter greater protection.

3. Overcoming Potential Litigation-Related Threats of Disclosure Right of Public Access. In addition to the threats of disclosure posed by FOIA requests and FDA use of the information, litigation proceedings, and specifically discovery requests, pose a third potential threat of disclosure. For example, if a generic manufacturer were to be sued by a competitor or third party, the generic manufacturer will be concerned that a bioequivalency trade secret could be subject to disclosure through a discovery request. While the Federal Rules of Civil Procedure contain specific provisions to protect litigating parties from the disclosure of trade secrets during the discovery process,[197] generic manufacturers will want to take special precautions in order to receive full protection for their bioequivalency tests. Case law can additionally protect a

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[192] *See supra* notes 84–85 and accompanying text.
[193] *See supra* notes 85–104 and accompanying text.
[194] *Ruckelshaus*, 467 U.S. at 1002.
[195] *Id.* at 998.
[196] *Id.* at 1008.
[197] FED. R. CIV. P. 26(c)(1)(G); *id.* § 45(d)(3)(B).

generic manufacturer's bioequivalency tests from litigation-related threats of disclosure.[198]

The threat of trade secret disclosure posed by the discovery process can be very serious because of the common law right of public access.[199] As the court notes in *Nycomed*, "The courts have long recognized a common law right of public access to judicial documents."[200] The primary theory behind the doctrine of the right of public access is related to the desire for the general public to perceive the court as an independent and legitimate body.[201] The Second Circuit has noted, "The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat and requires rigorous justification."[202] Thus, courts are strict about maintaining public access to judicial documents in order to maintain legitimacy and provide information for the general public. However, the court's desire conflicts with a generic drug manufacturer's interest in keeping information about bioequivalency tests hidden.

If a trade secret cannot withstand the common law right of public access, trade secret protection is of little use to generic manufacturers who face a discovery request by an opposing party for documents containing information related to bioequivalency testing methods. Although the common law right of public access can make the process of protection tricky for generic manufacturers, generic manufacturers can use the Second Circuit's three part test to determine whether a judicial document should be susceptible to the common law right of public access[203] in order to argue against disclosure.

The Second Circuit has stated that when judicial documents are requested, the presumption is that they are susceptible to public access.[204] Courts do err on the side of disclosure, but the common law right of public access is not absolute.[205] The Second Circuit's test to determine whether a judicial document is subject to the common law right of public access, as mentioned previously, involves three steps[206]: "First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial

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198 *See, e.g.*, Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.).

199 *Id.*

200 *Id.* at *7 (quoting Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2006)).

201 *Id.*

202 *Id.* (quoting United States v. Aref, 533 F.3d 72, 83 (2d Cir. 2008)).

203 *See supra* notes 128–29.

204 *See* United States v. Amodeo, 71 F.3d 1044, 1047–49 (2d Cir. 1995).

205 *See* Nixon v. Warner Commc's, Inc., 435 U.S. 589, 598 (1978).

206 Stern v. Cosby, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007). *See also supra* notes 128–29.

documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it."[207]

It is likely that, were the situation to arise, a generic manufacturer could successfully argue that a bioequivalency test protected as a trade secret should not be susceptible to the common law right of public access under the Second Circuit's analysis.[208] Looking at the first factor—"whether the documents were judicial documents to which the public had a right of access"[209]—a manufacturer could likely end the inquiry here. The definition of "judicial documents," as discussed in Part II.C,[210] is "relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies."[211] Thus, the only way that the definition would apply is if the documents with the relevant trade secret information were requested by or submitted to a court, which is not likely to be necessary unless the lawsuit concerns the bioequivalency testing method itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court's reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

Turning to the second factor, "the weight of the presumption of disclosure,"[212] a generic manufacturer would again have a strong argument against disclosure. As the court notes, "[T]he weight of the presumption depends on the 'role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the

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[207] *Stern*, 529 F. Supp. 2d at 420 (quoted in Nycomed US, Inc. v. Glenmark Generics, Inc., 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.)) (internal quotation marks omitted).

[208] *See supra* notes 128–29.

[209] *See supra* notes 128–29.

[210] *See supra* note 127.

[211] Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 122 (2d Cir. 2006) (quoting FTC v. Standard Fin. Mgmt. Corp., 830 F.2d 404, 409 (1st Cir. 1987)).

[212] *Stern*, 529 F. Supp. 2d at 420.

federal courts.' "[213] In other words, due to the high value of a bioequivalency test being kept a secret from competing manufacturers, the presumption of disclosure by the court would not be high and would favor the position of a generic manufacturer. The court further states the inquiry is often based largely on whether the information sought to be disclosed is germane to the litigation, especially if the information is used for a motion to dismiss.[214] Thus, for the purposes of a generic manufacturer protecting a bioequivalency test, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure. Furthermore, keeping in mind the purpose of the doctrine, it makes sense that the presumption is stronger when the information is related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, when looking at the third factor—competing considerations against the presumption[215]—it is likely that the generic manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As mentioned above, if courts will disclose lucrative, competition-driving methods and formulas to the public during litigation, generic manufacturers seeking protection will not seek judicial remedies. Furthermore, a manufacturer's active and vigorous defense of a trade secret is itself evidence of its value. If public disclosure via the common law right of public access causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret,[216] the presumption would favor disclosure. As demonstrated in *Momenta*, bioequivalency tests offer a competitive advantage to generic companies who develop them.[217] Because so much of the generic manufacturer's competitive advantage is stored in the bioequivalency test, the court would be reticent to subject this precious and valuable information to judicial disclosure.

For example, in *Nycomed*, the defendant sought to have the plaintiff's brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential.[218] Defendant Glenmark argued that because

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[213] Nycomed US, Inc. v. Glenmark Generics, Inc., No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788, at *9 (E.D.N.Y. 2010) (quoting United States v. Amodeo, 71 F.3d 1044, 1049 (2d Cir. 1995)) (internal citations omitted).

[214] *Id.*

[215] *Id.* at *8.

[216] *See, e.g.*, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351 (Fed. Cir. 2012).

[217] *Id.*

[218] *Nycomed*, 2010 U.S. District LEXIS 20788, at *12.

two paragraphs of the plaintiff's motion contained confidential information related to Glenmark's ANDA, this information was exempt from public disclosure.[219] The court, however, disagreed. This situation is easily distinguishable from the hypothetical situation in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a bioequivalency test protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if it was actually a secret. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief; surely an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place, if the alleged trade secret were really a secret. After reviewing the FDA's relevant provisions regarding the disclosure of pending ANDA's, the court notes, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential."[220] The court also noted that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access.[221] Thus, so long as the generic manufacturer actually treats the bioequivalency test information allegedly within the scope of the common law right of public access as a legitimate secret, the presumption against disclosure during litigation should cut in favor of the generic manufacturer.

In addition to the potential for disclosure due to a competitors assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to generic manufacturers who seek to protect their bioequivalency tests. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure.[222] However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery.[223] Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,'[224] and often work together to protect parties from disclosure.[225]

In *Massey Coal Services, Inc.*, for example, the court explained the circumstances under which a court can issue a protective order pursuant to Rule

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[219] *Id.* at *15.
[220] *Id.* at *16.
[221] *Id.*
[222] Paulsen v. Case Corp., 168 F.R.D. 285, 289 (C.D. Cal. 1996).
[223] Hamilton v. State Farm Mut. Auto. Ins. Co., 204 F.R.D. 420, 422 (S.D. Ind. 2001).
[224] *See* FED. R. CIV. P. 26, 45; *see also* text accompanying notes 131–36 for a review of rules 26 and 45.
[225] *See generally In re* Fosamax Prods. Liab. Litig., No. 1:06-MO-1789(JCF), 2009 U.S. Dist. LEXIS 70246, at *30 (S.D.N.Y.).

26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation.[226] The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation.[227] The defendants manufactured and installed piping that the plaintiff used in its coalmines; when the pipes failed, the defendants admitted there was a problem but would not provide further information.[228] Before the hearing, the judge issued a protective order for "documents or other materials . . . subject to disclosure . . . [that are] confidential and should not be disclosed other than in connection with this action."[229] The defendant disclosed to the plaintiffs several documents marked 'CONFIDENTIAL' per the protective order, a few of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Because the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority.[230] The defendant objected, invoking protection from Rule 26(c)(1)(G)[231] and arguing that the documents contained commercially valuable information.[232] For the purposes of analysis, the court noted that Rule 26(c)(1) "treats equally a trade secret or other confidential commercial information."

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1),[233] but the reasoning of the court is helpful in understanding the scope of the protection offered under 26(c)(1). In order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show "good cause" for protection, including, most relevantly, "undue burden or expense."[234] Essentially, the defendants in this case argued that "severe economic damage" would result from disclosure.[235] However, the court noted, "Broad allegations of harm, unsubstantiated by specific examples . . . do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle."[236] Additionally, the court stated that the

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226 Massey Coal Servs., Inc. v. Victaulic Co. of Am., 249 F.R.D. 477 (S.D.W. Va. 2008).
227 *Id.* at 478.
228 *Id.*
229 *Id.* at 479.
230 *Id.*
231 *Id.* at 482 (internal quotations omitted) (internal citations omitted).
232 *Id.*
233 *Id.* at 484.
234 *Id.* at 480; Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1987) (addressing the "standard for determining whether [d]efendants have shown good cause for a protective order" (citations omitted))). *See also* FED. R. CIV. P. 23(c)(1); *supra* text accompanying note 134.
235 *Massey Coal Servs., Inc.*, 249 F.R.D. 477.
236 *Id.* at 481 (citation omitted).

defendants had made no showing that they had undertaken efforts to keep the documents a secret,[237] that the defendants had not objected to disclosure of the documents to the plaintiffs, that the documents were contained in the court's public record, and that the defendants did not file a motion to seal the documents.[238] In light of these facts, the court reasoned that the documents were not commercially valuable and were not protectable.[239] The trial judge further stated that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure.[240]

In light of the *Massey* court's holding and reasoning, if a generic manufacturer protecting a bioequivalency test via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense."[241] The manufacturer should provide the court with "specific examples or articulated reasoning"[242] that disclosure of the trade secret would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle."[243] Generic manufacturers should also consider factors commonly used to measure secrecy, found in the Restatement of Torts. Such factors can include:

> [T]he extent to which the information is known by employees and others involved in the business . . . the extent of measures taken by the business to guard the secrecy of the information . . . the value of the information to the business and to its competitors . . . and the amount of effort or money expended in developing the information.[244]

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[237] *Id.* at 483.
[238] *Id.* at 484.
[239] *Id.* at 482–83.
[240] *Id.* at 484.
[241] *See* Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1987); *see also* FED. R. CIV. P. 26(c)(1).
[242] *Cipollone*, 785 F.2d at 1121.
[243] *Id.*
[244] *Massey Coal Servs., Inc.*, 249 F.R.D. at 482.

Again, since bioequivalency tests take substantial time, effort, and funding to create, they are critical to a generic manufacturer's market competitiveness.[245] Therefore, the manufacturer should take great care in maintaining their secrecy, for example, by limiting the number of employees who have the formulas, making employees sign confidentiality agreements and covenants not to compete, and maintaining a financially reasonable amount of computer system security. If a generic manufacturer is sued, it should be fairly simple to demonstrate to the court that documents containing the specific bioequivalency formula should either not be disclosed because they are not germane to the lawsuit, or that they should be privileged and confidential due to their economically valuable nature.

In addition, Rule 45 of the Federal Rules of Civil Procedure,[246] which governs subpoenas, could also benefit a generic manufacturer seeking to protect a bioequivalency test through trade secret law during litigation. A generic manufacturer's bioequialency test trade secret will lose its value if disclosed; given the test's high value, generic manufacturers will want to be aware of the risk of being subpoenaed so that they can demonstrate, if necessary, why a bioequivalency test trade secret should not be disclosed. When determining whether or not to quash a subpoena that could potentially pose a threat of disclosure to a generic manufacturer's bioequivalency test trade secret, the court will balance the burden of disclosure with the potential need/use of the information.[247]

Although there is also no per se protection for trade secrets under Rule 45, it is likely that a generic manufacturer would be able to withstand disclosure of a bioequivalency test in the event of a subpoena. For example, *In re Fosamax* demonstrates that drug manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued defendant drug company, Merck & Co., alleging that a drug they manufactured, Fosamax, caused adverse side effects.[248] The plaintiffs issued a subpoena to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the direction of the FDA.[249]

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[245] *See* Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1351–52 (Fed. Cir. 2012); Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013).

[246] FED. R. CIV. P. 45.

[247] *See supra* notes 138–41 and accompanying text.

[248] *In re* Fosamax Prods. Liab. Litig., No. 1:06-MO-1789(JFK)(JLF), 2009 U.S. Dist. LEXIS 70246, at *26 (S.D.N.Y. Aug. 4, 2009).

[249] *Id.* at *28.

Dr. Psaty moved to quash the subpoena under Rule 45(d)(3)(B),[250] alleging that he never studied the drug in question;[251] furthermore, the defendant urged that even if Dr. Psaty testified, it was unclear whether he would be required to disclose confidential information or trade secrets.[252] In making its decision, the court tried to balance the burden between necessity of the testimony and the undue burden on the defendant to produce the information, ultimately quashing the subpoena.[253] In considering whether there is an undue burden on the defendant, the court assesses the personal hardship to the party protecting the information and the wider social consequences of disclosing the information.[254] Here, the court noted that if Dr. Psaty were required to testify, "the resulting social impact would be far more serious. Compelling testimony from a third party researcher risks chilling participation in beneficial public research."[255] Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

When comparing this case with the potential disclosure of a generic manufacturer's bioequivalency test, generic manufacturers who receive subpoenas would likely not be required to disclose trade secrets if called to testify. Even if the testimony sought were important to the case, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the generic manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage.[256] In addition, the consideration of wider social impact would weigh in favor of suppressing the subpoena, because requiring generic drug manufacturers to disclose trade secrets could have a chilling effect on beneficial scientific research.

Generic manufacturers provide a valuable service to consumers by lowering the cost of drugs. However, because the Federal Circuit's expansive reading of

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[250] *Id.* at *27. *See also* FED. R. CIV. P. 45(d)(3)(B)(i)–(ii) ("To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information; or (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.").

[251] *In re* Fosamax Prods. Liab. Litig., 2009 U.S. Dist. LEXIS 70246, at *28.

[252] *Id.* at *30.

[253] *Id.* at *33–34.

[254] *Id.* at *34.

[255] *Id.* at *35.

[256] *See, e.g.*, Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012).

the safe harbor provision in *Momenta v. Amphastar* gives generic manufacturers little protection for their bioequivalency tests through patent law,[257] the incentive to produce generic drugs will likely decrease if another method of protection is not found. Although trade secret law does not provide per se protection from disclosure,[258] generic manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and litigation.

Although FOIA encourages the broad disclosure of government-held information, a generic manufacturer can demonstrate to the FDA's FOIA office that bioequivalency test trade secrets are immune from disclosure. The generic manufacturer can point to the definition of trade secret adopted in *Public Citizen Health* to argue that a bioequivalency text qualifies as a trade secret, exempting it from disclosure. Generic manufacturers can also overcome the threat of disclosure posed by the FDA's potential use or disclosure of the information, because the FDA is only allowed to disclose protected information submitted to it by a third party under limited circumstances. Because generic manufacturers have a property interest in their bioequivalency test trade secrets, the FDA has a limited amount of power to disclose this information; so long as a generic manufacturer treats the bioequivalency test as a trade secret, the threat of disclosure by the FDA is manageable. Finally, litigation-related threats of disclosure, specifically the common law right of public access and discovery requests made by parties to a litigation, can also be overcome by generic manufacturers. The test developed by the Second Circuit in *Stern v. Cosby* can be used to show that the presumption in favor of disclosure present in the common law right of public access can be avoided by generic manufacturers protecting bioequivalency tests as trade secrets. Furthermore, generic manufacturers could also protect their bioequivalency test trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. This Note has therefore demonstrated that generic manufacturers could successfully protect their bioequivalency research and development investments from use by competitors through the use of trade secret law.

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[257] *Id.* at 1361.

[258] United States v. Int'l Bus. Mach. Corp., 67 F.R.D. 40, 42 n.1 (S.D.N.Y. 1975) (holding that "trade secrets and other confidential commercial information enjoy no privilege from disclosure although courts may choose to protect such information").

IV. CONCLUSION

Altogether, this Note has explored the impact and the consequences of the recent holding in *Momenta* and one potential solution to the problems created by the Federal Circuit.[259] The *Momenta* majority held that a generic manufacturer who uses the patented bioequivalency test of a competitor is protected from liability by way of the safe harbor provision of the Hatch Waxman Act.[260] As Chief Judge Rader points out in his dissent, the majority's holding effectively renders all patents on bioequivalency testing methods worthless,[261] an effect confirmed by later proceedings.[262] In light of the *Momenta* holding, generic manufacturers are now in need of a way to protect their bioequivalency testing methods from use by their competitors. This Note has demonstrated that trade secret law can provide a viable alternative to patent protection for generic manufacturers, at least in the absence of any action by Congress to address the Federal Circuit's expansive reading of the safe harbor provision in *Momenta v. Amphastar*.

Generic manufacturers can protect their bioequivalency tests through trade secret law by overcoming obstacles in three potentially threatening contexts. Generic manufacturers can overcome the threat of disclosure from a FOIA request by arguing that bioequivalency tests fit within the scope of the definition of "trade secret" and constitute commercially valuable information. Second, generic manufacturers can withstand the threat of disclosure through the FDA's own use of the information by again arguing that a bioequivalency test constitutes a trade secret, under the specific FDA definition and by showing positive steps taken to treat the information as a secret, meeting the Second Circuit's test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, generic manufacturers can use trade secret law to protect bioequivalency tests despite the threat of disclosure from litigation by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas.

Ideally, Congress will recognize the Federal Circuit's unfortunate holding in *Momenta* with corrective legislation to restore the power of patent protection to

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[259] Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1368 (Fed. Cir. 2012).
[260] *Id.* at 1361.
[261] *Id.* at 1362 (Rader, J., dissenting).
[262] *See* Teva Pharm. USA, Inc. v. Sandoz Inc., 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

generic manufacturers. However, in the meantime, or indefinitely into the future if necessary, trade secret law can provide an alternative to patent protection for generic manufacturers who desire to protect their bioequivalency tests from the hungry eyes of their competitors.

From: Tshudy, Trisha R
To: Williams, Laura H
Subject: Re: Honor Code
Date: Tuesday, January 4, 2022 12:02:38 PM
Attachments: Research Paper Outline 2.docx

Dear Dean Williams,

So far without even using Lexus and Westlaw, I have culminated a list of 33 papers/articles/analyses/etc. that directly align with the information in mine. I wanted to send some of them over so you can start to get an idea of how written about this topic has become. If you can provide me a narrower view of what part of my paper is exactly in question, I can help reduce the sources for your viewing purposes or even direct you to more specific ones since I have no idea which would be question. I am also attaching my refined outline where Professor Gould advised me on what specific direction, he wanted me to go as well as quite a few other particulars. I also wrote in a few responses while I am trying to determine what section is in question. Nearly the entire second section was based on class work, and I explained that I did write analyses and responses to Professor Gould for participation credit, but that those were just a backup if we had technical difficulties, so it was my in-class presentation that counted. Therefore, I do not believe that is considered a violation from multiple submissions of my same observations, because it only counted once. The second section is even more common and generic whether it's just going through rules of civil procedure applying to trade secrets or even when it receives the added specificity of the biotech/pharmaceutical lens that Professor Gould specified was necessary. Unlike the first section where those cases were read in class, the cases in the second section were ones that were commonly cited and reiterated when explaining the implications. The analysis for the three-part test alone is covered by a multitude of articles. Therefore, to prevent getting bogged down, I went directly to the cases themselves and important takeaways, headnotes, and quotes that I am sure everyone else recognizes and pulls out as well. Again, I am happy to continue working, but if there is a way to narrow down what is in question, that would be much appreciated because again, I can come up with well over thirty resources immediately that I can find comparable sections or organization with on the exact topic. Also, let me know if you would like information on who I specifically talked to regarding my concerns and the feeling that Professor Gould really commandeered my topic selection into one that I had no idea was written about so extensively and comprehensively. I can also list the steps I took to try to prevent any issue since it was a slight concern of mine. Moreso, I was concerned about making sure my resource list was cited correctly, but I would be surprised if there is any student who fears an accusation of an honor code violation. Even earlier this semester for my unincorporated business class, Professor Prince thought I had copied on an assignment until I showed her that the reason it was so unique was because it was about a real-life example of my friend who is a falconer that I used as inspiration. I even prepared my internet history and everything to show her that I didn't even glance at a comparable resource. I took my knowledge of her story and Professor Prince's PowerPoint (simply to make sure the hypo I created was covered) but apparently it was too entrepreneurial that she thought it was copied before I sent her everything, she needed to confirm without a doubt that I did not. Anyway, I'll keep working and look for your response. Again, there are so many that overlap, and I read so extensively prior to topic selection and then refinement by Professor Gould that I can easily show multiple sources that took the exact path of organization since that is literally what the emerging doctrine entails. But again, it is all in my own words and everything that ties to a specific article or statute is cited. Thank you so much for your time.

With Much Appreciation,

Trisha Tshudy

1. Robert Graham Gibbons, Bryan J. Vogel, The Increasing Importance of Trade Secret Protection in the Biotechnology, Pharmaceutical and Medical Device Fields, 89 J. Pat. & Trademark Off. Soc'y 261, 285 (2007)

2. Drugmakers, pharma groups ask justices to end 'blocking patent' doctrine, 2019 WL 2147798

3. § 4:23. Patenting vs. maintenance as a trade secret, 1 Pat. L. Fundamentals § 4:23 (2d ed.)

Three cases that also came up, but because they were written about so much and I had the option of using the cases from class, that I would just use those instead. But these are the three….

1) Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 189 L. Ed. 2d 296, 110 U.S.P.Q.2d 1976 (2014). *See* §§ 7:5 &

20:119, *infra*.

2) Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1296–98, 182 L. Ed. 2d 321, 101 U.S.P.Q.2d 1961, 1967–69, 90 A.L.R. Fed. 2d 685 (2012). *See* § 7:4.50, infra.

3)Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–19, 186 L. Ed. 2d 124, 106 U.S.P.Q.2d 1972, 1979–81 (2013). *See* § 7:4.50, infra.

4. Northrop, Protecting Software: The Trade Secret or Patent Decision Tree, 88 Pat., Trademark & Copyright J. 222 (May 16, 2014); Bason, Intellectual Property/Trade Secrets: Panelists Say Alice, AIA Among Factors Driving Would-Be-Patentees to Trade Secrets, 89 Pat., Trademark & Copyright J. 686 (Jan. 16, 2015); Jeffrey Mordaunt & Joshua Swedlow, *Why Trade Secret Litigation Is On The Rise*, Law 360, Nov. 4, 2017.

5. Hannah-Alise Rogers, Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar, 22 J. Intell. Prop. L. 209, 214 (2014)

6. John T. Aquino, *Trade Secrets/Biotechnology: Attorney Says Federal Trade Secret Law May Better Protect Biotech Processes*, 91 Pat., Trademark & Copyright J. 1811 (Apr. 22, 2016).

7. Trade Secrets Protection in the Pharmaceutical Industry: Exploring Best Practices https://knowledgewebcasts.com/know-portfolio/protection-in-the-pharmaceutical-industry-cle/

8. https://www.winston.com/images/content/2/0/v2/203824/trends-in-trade-secret-litigation-report-2020.pdf

9. APPENDIX III -- FDA PREAMBLE, GUIDANCE AND OTHER ADVISORY DOCUMENTS, 2006 WL 3436684 (FDA info on requests, but did not go into specificity or use any ideas concepts or quotes that were specifically presented. It was simply background.)

10. Trends in Trade Secret Litigation Report 2020 https://www.stout.com/en/insights/report/trends-in-trade-secret-litigation-report-2020?gclid=Cj0KCQiA_c-OBhDFARIsAIFg3ew-zEfrAdl3FOnNxQPoFYm-AxG1fzV10T7-XKbXxF5dUP2CDORdxZ4aAmcNEALw_wcB

11. Trade Secrets in Life Science and Pharmaceutical Companies https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382727/(Contains all the background info on legislation and trade secret definitions. Unfortunately, the cases supplied dealt with misappropriation which Professor Gould did want me to concentrate on because it could be assumed to be known or wasn't worth analysis.)

12. Biotechnology and Trade Secret Protection https://www.robinskaplan.com/-/media/pdfs/publications/biotechnology-and-trade-secret-protection.pdf?la=en

13. The Curious Cases of Trade Secret Identification https://www.arnoldporter.com/-/media/files/perspectives/publications/2021/05/the-curious-cases-of-trade-secret-identification.pdf

14. All About What Constitutes Trade Secrets: Are Documents In Discovery Necessary?

by Romy Jurado | Mar 12, 2021 | Business https://jflawfirm.com/all-about-what-constitutes-trade-secrets-are-

documents-in-discovery-necessary/

15. An Epic Trade Secret Mistake? Why Third Parties to Litigation May be at Risk of Losing Trade Secret Protections June 7, 2021By Carolyn Wimbly Martin and Robert Piper https://www.lutzker.com/an-epic-trade-secret-mistake-why-third-parties-to-litigation-may-be-at-risk-of-losing-trade-secret-protections/

16. North America: Discovery in Trade Secret Cases https://www.globalcompliancenews.com/2021/04/01/north-america-discovery-in-trade-secrets-cases-11032021/

17. Trade Secret Identification: Prerequisite to Discovery March/April 2015 IP Litigator By John F. Hornick; Margaret A. Esquenet https://www.finnegan.com/en/insights/articles/trade-secret-identification-prerequisite-to-discovery-1.html

18. Discovery of Trade Secrets Santa Clara Law Journal https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1152&context=chtlj

19. Trade Secrets: 10 Keys to Successful Litigation by Jessica Brown and Tafari Lumumba https://www.gibsondunn.com/wp-content/uploads/documents/news/Brown-Lumumba-Trade-Secrets-10-Keys-to-Successful-Litigation-Colorado-Lawyer-Jan.-2016.pdf

20. The "Attorneys' Eyes Only" Designation and Other Disclosure Restrictions in Trade Secrets Litigation https://frostbrowntodd.com/the-attorneys-eyes-only-designation-and-other-disclosure-restrictions-in-trade-secrets-litigation/

21. Loss of Trade Secrets through Inadvertence https://cyber.harvard.edu/openlaw/DVD/research/EFF_General_8.html

22. Life, Liberty, and Trade Secrets 70 STAN. L.REV. 1343 (2018) https://review.law.stanford.edu/wp-content/uploads/sites/3/2018/06/70-Stan.-L.-Rev.-1343.pdf (Discovery, Subpoenas, Protective orders, sealing, and courtroom closures, The Trade Secret Privilege Overprotects Intellectual Property, Substantive trade secret law, The purposes of trade secret law, Innovation concerns, The Scope and Purpose of Privilege Law, Judicial authority and a criminal trade secret privilege, Sensitive information inside and outside the courts)

23. Trade Secrets Challenges for Patent Prosecutors and Litigators https://www.stoel.com/legal-insights/article/trade-secrets-challenges-for-patent-prosecutors-an

24.Protecting Trade Secrets Disclosed To The FDA By Douglas Nemec, William Casey and Tara Melillo (February 13, 2018, 10:50 AM EST) file:///C:/Users/ttshu/Downloads/Protecting_Trade_Secrets_Disclosed_to_the_FDA.pdf

25. Protecting Trade Secrets in the Medical Product Approval Process by Kristan Lansbery https://www.fdli.org/2018/04/update-protecting-trade-secrets-medical-product-approval-process/

26. Protecting Trade Secrets in the Pharmaceutical Industry in the Age of COVID-19 by Julie McCarthy https://www.seyfarth.com/dir_docs/publications/ProtectingTradeSecretsinthePharmaceuticalIndustryintheAgeofCOVID-19.pdf

27. Tips for Ensuring Your Competitors Do Not Steal the Valuable Fruits of Your Research and Development By Katherine Perrelli on March 28, 2014 https://www.tradesecretslaw.com/2014/03/articles/trade-secrets/tips-for-ensuring-your-competitors-do-not-steal-the-valuable-fruits-of-your-research-and-development/

28. The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines by Christopher J. Morten* and Amy Kapczynski**

https://29qish1lqx5q2k5d7b491joo-wpengine.netdna-ssl.com/wp-content/uploads/2021/04/3-Morten-and-Kapczynski-postEIC.pdf

29. Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 Marq. Intellectual Property L. Rev. 33 (2014).
Available at: https://scholarship.law.marquette.edu/iplr/vol18/iss1/1

30. McGarity, Thomas O., and Sidney A. Shapiro. "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies." *Harvard Law Review*, vol. 93, no. 5, The Harvard Law Review Association, 1980, pp. 837–88, https://doi.org/10.2307/1340420.

31. Comments on Food and Drug Administration Transparency Task Force; Public Meeting and Request for Comments; Docket No. FDA-2009-N-0247; 74 Fed. Reg. 26,712 (June 3, 2009).
https://www.fdanews.com/ext/resources/files/archives/f/FDA-2009-N-0247-0107.1.pdf

32. DETERRING FRAUD: MANDATORY DISCLOSURE AND THE FDA DRUG APPROVAL PROCESS LIORA SUKHATME* https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-82-4-Sukhatme.pdf

33. Intellectual Property Protection for Biologics Megan Brewster https://repository.upenn.edu/cgi/viewcontent.cgi?article=1035&context=ace

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From: Williams, Laura H <lhw10@psu.edu>
Sent: Monday, January 3, 2022 5:39 PM
To: Tshudy, Trisha R <trt5096@psu.edu>
Cc: Sondhi, Sabrina <szs7112@psu.edu>
Subject: Honor Code

Hi Trisha-
Thanks for talking with Prof. Sondhi and me this afternoon.

The Honor Code can be found here: https://dickinsonlaw.psu.edu/honor-code#1.1. In the event you have trouble accessing it, I have attached a copy. If you have any questions about the Honor Code, please let me know.

I will need your information ASAP. This is a very important matter. Thanks for your understanding.
Dean Williams

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University

150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

Legal Issues Arising from the Emergence of Trade Secrets as Patent Alternative

I. Introduction Biotech Significance

A. History (ONLY WHATS NEEDED TO SUPPORT THIS DISCUSSION, removed topic because it was recommended to add the information through footnotes instead, but was too complicated)

1. Competition with Patents: Manufacturing Processes vs. Publicly Available Product (Professor Gould deemed unnecessary)

2. Legislative and Statutory Protection (Professor Gould deemed unnecessary)

a. Defend Trade Secrets Act of 2015

b. Uniform Trade Secrets Act

I. REVISED INTRO according to Professor Gould's input. Why Care? Overall intro. Introduce Roadmap.(Unfortunately, my roadmap somehow got deleted, but the rest was included).

1. Emerging Issues with Patent Protection

a. The patent system's failure to adjust to product and method refinement and recognize the value of process is a key force behind the movement of manufacturers to the use of trade secrets as a patent alternative.(This entire section was included in more articles, papers, and responses than I can count and really constitutes background information and concerns that is mentioned by most of the papers I read in the very beginning before I even chose this as my research paper topic. This is so common and was based on the general knowledge and history I gained both from class, readings, and original basic topic research that I didn't have a particular article to cite because its borderline generally known information that Professor Gould told me to limit nearly assume it's common knowledge.

-Exclusivity period

-Dual Patent

-Product and Process (In re Wands)

-Reverse-engineering

b. Variations in patent scope are an additional cause for manufacturers to move to trade secret dependency. We did this all in class, so my words and the cases I used were directly tied to my observations that I made in response to the course work. I did not believe this is considered a violation because even though I sent Professor Gould the same personal observations I had to the cases that I also included in my paper, my actual speaking to my class counted as my participation not my email. I sent the email just in case we encountered technical difficulties, but we did not so my verbal response was credited for the participation requirement not what I wrote. Therefore, I believe I was allowed to use my previous write-up of the case since it was not actual counted as and assignment or submitted for credit.

-Hatch-Waxman Act

-Momenta

-Pfizer v. Apotex

-FTC vs. Actavis

*Transition Paragraph!!! Connect the migration to Trade Secrets and the emerging issues that come from that!

III. Trade Secret Law and the Potential Threats of Disclosure: Emerging Issues as Reflected in Litigation (what you might be forced to disclosed in litigation) see FDA filings, big discovery fights, two layers of protective orders, discovered but layered and kept confidential, force discovery but allow only outside council to see, polymorph cases patent cases, inhouse lawyers shouldn't be allowed to see

these things because of involvement, inhouse lawyers might be talking to regulatory groups. Not fair to make their challenges via the FDA. (Greatly emphasized by Professor Gould!!!)(This entire section is repeated across so many articles, papers, and trade secret litigation advertisements that I followed the sample paper example and included the resources that I specifically drew from. My outline is a very common list of what to watch out for and any sources that are provided that fell into the Biotech Pharmaceutical sphere, I looked in to. From my source list you can see that there were standouts. Even the organization of issues that are arising from trade secret litigation were not unique to any paper. They almost always if not always had them listed sequentially in the order you would expect them to come up. Before Professor Gould corrected my paper, I had a list of issues like NDAs and other protection policies, but again he specified that this is what he wanted me to write about instead. Since the purpose of the paper is to highlight the emerging issues, I used the most general and reoccurring ones that had definite biotech/pharmaceutical cases to back them. So that's why you don't see any incredibly unique ones with specific sources because my paper was specific to the trends and Professor Gould told me not to get bogged down by intricacies, but make sure our papers are concise and applicable. He said he wanted to see strong case analysis that has strong implications and broad applications, so I chose the cases that have had the greatest influence on trade secret litigation so far. Unfortunately, when your professor also requires them to be specific to biotech/pharma it really set me up additionally to be bouncing between other pieces of writing that I only found when I chose to search and see if there was any bigger picture items or cases that I missed.

A. Obtaining Trade Secret Protection/Proper Compliance with Trade Secret Definitions -no registration. Dependent on ability to be properly written and effort to protect them from being maintained. Unique to pharmaceuticals is FDA review and approval still being necessary so adds a unique risk of disclosure to trade secrets. (12-20)

B. Freedom of Information Act and FDA's disclosure policy (21-38)

C. Right to Public Access (39-50)

-Nycomed US

-Lugosh v. Pyramid Co. of Onondaga

-Stern Cosby (three-part test)

D. Notice Requirements and Discovery Requests (Rules 26 and 45) (54-64)

-Massey Coal Services, Inc.

E. Subpoenas (Rule 45) (65-73)

-In re Fosamax

IV. Conclusion

Originally, I had more general cases regarding trade secrets included in my outline, some of which I included below, before Professor Gould specifically told me that I need to find cases and source that are more specific to pharmaceutical and biotech law instead of generic to avoid making it look like a business paper. This was an additional complication because there are only so many cases to choose from and again, all the papers and even news articles follow the same organization and info, so I tried to pull the same information from each case that I needed but put it into my own words. I even emphasized to Professor Gould this concern that it is going to be difficult to avoid the business paper feel because the more specific I get, the harder it is to differentiate my own observations and take aways from others. Everyone is looking at the same cases and pulling out the same quotes and information to use in their insights and reflections.

1. In re Michelin N. Am., Inc., 2016 Tex. App. LEXIS 2467. When the party resisting discovery establishes that the information constitutes a trade secret, the burden shifts

to the requesting party to establish that the information is necessary for a fair adjudication of its claim or defense.

2. Jennifer S. Sickler and Michael F. Heim, The Impact of Rule 76a: Trade Secrets Crash and Burn in Texas, 1 Tex. Intell. Prop. L.J. 95, 97 (1993) (The authors conclude that Tex. Rule of Civ. Proc. 76a poses a threat to trade secrets that are produced during discovery. Rule 76a addresses the sealing of court records.
3. The Honorable Craig Smith, Grant Schmidt and Austin Smith, Essay, Finding a Balance Between Securing Confidentiality and Preserving Court Transparency: A Re-Visit of Rule 76a and Its Application to Unfiled Discovery, 69 SMU L. Rev. 309 (2016)
4. James J. Watson, Annot., Discovery of Trade Secret in State Court Action, 75 A.L.R. 4th 1009 (1990).

V. Resources

-I created a massive resource list of all the resources I came across and then tried to take out any that were unused. Because so many places cited the same cases with the same observations, I tried to site the cases themselves directly instead of cite references because they were so similar across papers and documents and articles, that if I cited it from one, it could appear to be the miscite from others. When there are so many different sources with the same take away and breakdown, it becomes a generalization about the case and so generalizations in my own words should not be infringements.

Footnotes: Additional facts, history, issues I don't have room to touch on.

Papers/Articles/Cases/Analyses that align:

1. Robert Graham Gibbons, Bryan J. Vogel, The Increasing Importance of Trade Secret Protection in the Biotechnology, Pharmaceutical and Medical Device Fields, 89 J. Pat. & Trademark Off. Soc'y 261,

285 (2007)(Was able to find applicable cases within the textbook so I don't believe any of these cases are in common, but an example of similar information across resources. I obviously did not use any of this within my paper, but there may be generalizations in common).

2. Drugmakers, pharma groups ask justices to end 'blocking patent' doctrine, 2019 WL 2147798

3. § 4:23. Patenting vs. maintenance as a trade secret, 1 Pat. L. Fundamentals § 4:23 (2d ed.)(Again, chose to use the cases in class instead of the commonly cited cases like Alice since there were alternative options for cases that fall under the biotech/pharmaceutical specificity. This was not the case for section III. But Section III was also a lot more generic and was in a tremendous number of articles and such.)

Three cases that also came up but I chose because they were written about so much and I had the option of using the cases from class, that I would just use those instead. But these are the three….

1) Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 189 L. Ed. 2d 296, 110 U.S.P.Q.2d 1976 (2014). *See* §§ 7:5 &20:119, *infra*.

2) Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1296–98, 182 L. Ed. 2d 321, 101 U.S.P.Q.2d 1961, 1967–69, 90 A.L.R. Fed. 2d 685 (2012). *See* § 7:4.50, infra.

3)Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–19, 186 L. Ed. 2d 124, 106 U.S.P.Q.2d 1972, 1979–81 (2013). *See* § 7:4.50, infra.

4. Northrop, Protecting Software: The Trade Secret or Patent Decision Tree, 88 Pat., Trademark & Copyright J. 222 (May 16, 2014); Bason, Intellectual Property/Trade Secrets: Panelists Say Alice, AIA Among Factors Driving Would-Be-Patentees to Trade Secrets, 89 Pat., Trademark & Copyright J. 686

(Jan. 16, 2015); Jeffrey Mordaunt & Joshua Swedlow, *Why Trade Secret Litigation Is On The Rise*, Law 360, Nov. 4, 2017.

5. Hannah-Alise Rogers, Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After Momenta v. Amphastar, 22 J. Intell. Prop. L. 209, 214 (2014)

6. John T. Aquino, *Trade Secrets/Biotechnology: Attorney Says Federal Trade Secret Law May Better Protect Biotech Processes*, 91 Pat., Trademark & Copyright J. 1811 (Apr. 22, 2016).

7. Trade Secrets Protection in the Pharmaceutical Industry: Exploring Best Practices https://knowledgewebcasts.com/know-portfolio/protection-in-the-pharmaceutical-industry-cle/

8. https://www.winston.com/images/content/2/0/v2/203824/trends-in-trade-secret-litigation-report-2020.pdf

9. APPENDIX III -- FDA PREAMBLE, GUIDANCE AND OTHER ADVISORY DOCUMENTS, 2006 WL 3436684 (FDA info on requests, but did not go into specificity or use any ideas concepts or quotes that were specifically presented. It was simply background.)

10. Trends in Trade Secret Litigation Report 2020 https://www.stout.com/en/insights/report/trends-in-trade-secret-litigation-report-2020?gclid=Cj0KCQiA_c-OBhDFARIsAIFg3ew-zEfrAdl3FOnNxQPoFYm-AxG1fzV10T7-XKbXxF5dUP2CDORdxZ4aAmcNEALw_wcB

11. Trade Secrets in Life Science and Pharmaceutical Companies https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382727/ (Contains all the background info on legislation and trade secret definitions. Unfortunately the cases supplied dealt with misappropriation which Professor Gould did want me to concentrate on because it could be assumed to be known or wasn't worth analysis.)

12. Biotechnology and Trade Secret Protection https://www.robinskaplan.com/-/media/pdfs/publications/biotechnology-and-trade-secret-protection.pdf?la=en

13. The Curious Cases of Trade Secret Identification https://www.arnoldporter.com/-/media/files/perspectives/publications/2021/05/the-curious-cases-of-trade-secret-identification.pdf

14. All About What Constitutes Trade Secrets: Are Documents In Discovery Necessary?

by Romy Jurado | Mar 12, 2021 | Business https://jflawfirm.com/all-about-what-constitutes-trade-secrets-are-documents-in-discovery-necessary/

15. An Epic Trade Secret Mistake? Why Third Parties to Litigation May be at Risk of Losing Trade Secret Protections June 7, 2021By Carolyn Wimbly Martin and Robert Piper https://www.lutzker.com/an-epic-trade-secret-mistake-why-third-parties-to-litigation-may-be-at-risk-of-losing-trade-secret-protections/

16. North America: Discovery in Trade Secret Cases https://www.globalcompliancenews.com/2021/04/01/north-america-discovery-in-trade-secrets-cases-11032021/

17. Trade Secret Identification: Prerequisite to Discovery March/April 2015 IP Litigator By John F. Hornick; Margaret A. Esquenet https://www.finnegan.com/en/insights/articles/trade-secret-identification-prerequisite-to-discovery-1.html

18. Discovery of Trade Secrets Santa Clara Law Journal https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1152&context=chtlj

19. Trade Secrets: 10 Keys to Successful Litigation by Jessica Brown and Tafari Lumumba https://www.gibsondunn.com/wp-content/uploads/documents/news/Brown-Lumumba-Trade-Secrets-10-Keys-to-Successful-Litigation-Colorado-Lawyer-Jan.-2016.pdf

20. The "Attorneys' Eyes Only" Designation and Other Disclosure Restrictions in Trade Secrets Litigation https://frostbrowntodd.com/the-attorneys-eyes-only-designation-and-other-disclosure-restrictions-in-trade-secrets-litigation/

21. Loss of Trade Secrets through Inadvertence https://cyber.harvard.edu/openlaw/DVD/research/EFF_General_8.html

22. Life, Liberty, and Trade Secrets 70 STAN. L.REV. 1343 (2018) https://review.law.stanford.edu/wp-content/uploads/sites/3/2018/06/70-Stan.-L.-Rev.-1343.pdf (Discovery, Subpoenas, Protective orders, sealing, and courtroom closures, The Trade Secret Privilege Overprotects Intellectual Property, Substantive trade secret law, The purposes of trade secret law, Innovation concerns, The Scope and Purpose of Privilege Law, Judicial authority and a criminal trade secret privilege, Sensitive information inside and outside the courts)

23. Trade Secrets Challenges for Patent Prosecutors and Litigators https://www.stoel.com/legal-insights/article/trade-secrets-challenges-for-patent-prosecutors-an

24. Protecting Trade Secrets Disclosed To The FDA By Douglas Nemec, William Casey and Tara Melillo (February 13, 2018, 10:50 AM EST) file:///C:/Users/ttshu/Downloads/Protecting_Trade_Secrets_Disclosed_to_the_FDA.pdf

25. Protecting Trade Secrets in the Medical Product Approval Process by Kristan Lansbery https://www.fdli.org/2018/04/update-protecting-trade-secrets-medical-product-approval-process/

26. Protecting Trade Secrets in the Pharmaceutical Industry in the Age of COVID-19 by Julie McCarthy
https://www.seyfarth.com/dir_docs/publications/ProtectingTradeSecretsinthePharmaceuticalIndustryintheAgeofCOVID-19.pdf

27. Tips for Ensuring Your Competitors Do Not Steal the Valuable Fruits of Your Research and Development By Katherine Perrelli on March 28, 2014
https://www.tradesecretslaw.com/2014/03/articles/trade-secrets/tips-for-ensuring-your-competitors-do-not-steal-the-valuable-fruits-of-your-research-and-development/

28. The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines by Christopher J. Morten* and Amy Kapczynski**
https://29qish1lqx5q2k5d7b491joo-wpengine.netdna-ssl.com/wp-content/uploads/2021/04/3-Morten-and-Kapczynski-postEIC.pdf

29. Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 Marq. Intellectual Property L. Rev. 33 (2014).
Available at: https://scholarship.law.marquette.edu/iplr/vol18/iss1/1

30. McGarity, Thomas O., and Sidney A. Shapiro. "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies." *Harvard Law Review*, vol. 93, no. 5, The Harvard Law Review Association, 1980, pp. 837–88, https://doi.org/10.2307/1340420.

31. Comments on Food and Drug Administration Transparency Task Force; Public Meeting and Request for Comments; Docket No. FDA-2009-N-0247; 74 Fed. Reg. 26,712 (June 3, 2009).
https://www.fdanews.com/ext/resources/files/archives/f/FDA-2009-N-0247-0107.1.pdf

32. DETERRING FRAUD: MANDATORY DISCLOSURE AND THE FDA DRUG APPROVAL PROCESS LIORA SUKHATME* https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-82-4-Sukhatme.pdf

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I. Introduction Biotech Significance

A. History (ONLY WHATS NEEDED TO SUPPORT THIS DISCUSSION)

1. Competition with Patents: Manufacturing Processes vs. Publicly Available Product

2. Legislative and Statutory Protection

a. Defend Trade Secrets Act of 2015

b. Uniform Trade Secrets Act

Introduction

Trade secret protection arises under state common law and state statutes. In general, a trade secret is information that is not generally known to the public and is maintained as a secret, and it provides a competitive advantage or economic benefit to the trade secret holder. Trade secrets can be worth tens or hundreds of millions of dollars, and damage awards in trade secret litigation have been high; often, there is a lot at stake. Obtaining a trade secret through "improper means" is misappropriation. If the alleged trade secret, however, was developed independently, known publicly, or not maintained as a secret, then those defenses may successfully overcome a claim for trade secret misappropriation. With today's interconnectedness in the biotechnology and pharmaceutical fields, more collaborations, joint ventures, and outsourcing arrangements among firms, and increased mobility of employees' careers,

life science companies need to not only understand how to protect their trade secrets, but also know how to defend against a claim for trade secret theft.

History

Trade secret law protects valuable information, so long as its owner makes reasonable efforts to maintain the information's secrecy. Trade secret protection is available under both state and federal law. The vast majority of states have adopted some version of the Uniform Trade Secrets Act, or UTSA. In 2016, Congress enacted the Defend Trade Secrets Act, or DTSA, which added federal protection for trade secrets based largely on concepts developed by state law.

The UTSA and the DTSA define a trade secret in two parts. First, a trade secret is any information that derives independent economic value from being secret. Second, an owner must take reasonable measures to maintain the information's secrecy. There's no registration or examination system for trade secrets. To obtain trade secret protection for qualifying information, an owner must make reasonable efforts to maintain the secrecy of protectable information.

Binary choice between trade secrets and patent law. Once information is disclosed publicly in a published patent application, it can't be maintained as a trade secret. Most patent applications are published 18 months after being filed, before an applicant knows for certain whether any patent rights will issue from the application. The choice to pursue patent protection over maintaining information as a trade secret therefore involves some risk.

II. Protective Measures

A. Physical Security

B. Digital Security

C. Legal Measures

§ 14.02 Disclosure and Protection of Trade Secrets Incident to Litigation

Discovery in trade secret litigation is routinely conducted under court protective orders. However, while commonly trade secret discovery arises in a dispute involving claims of misappropriation of trade secrets, or some other breach of duty, it also arises in other contexts, such as in product liability actions. There courts are hesitant to order disclosure. Thus, while in traditional trade secret and other cases, courts routinely require disclosure of relevant and material information, even though asserted to be a trade secret and even though the parties are direct competitors, subject to protective orders restricting use of the information acquired in discovery strictly for purposes of the litigation and frequently recognizing different levels of confidential information, subject to different access (e.g., attorneys and experts only) in other types of litigation, in which trade secrets are tangential (such as a product liability action in which product formulas are sought), courts hesitate before ordering production of trade secret matter, even subject to a protective order.

Courts typically limit disclosure of the defendant manufacturer's confidential information in personal injury/product liability actions only where plainly relevant and genuinely necessary for the discovering party to present its case.

Protective orders, although issued by the court, are typically negotiated by the parties. Courts intercede if the parties are unable to reach agreement. However, due to a growing "public" (read "media") concern that protective orders are used excessively, courts in some jurisdictions no longer automatically endorse party proposed protective orders.

Assuming, however, that, as is the case in virtually all trade secret disputes, a secrecy order is necessary, there are several basic strands. Access to the information disclosed is strictly limited, often in tiered levels (mentioned below) and is to be used solely for the purposes of the litigation. In many

instances, particularly where the parties are competitors, the court may require that outside counsel and opposing-party-approved experts be interposed between the parties so that principals or employees of the opposing parties do not have access to highly confidential information of the other. Often disclosure is two or three tiered, such as to (a) attorneys' (and experts') eyes only, (b) same plus designated employees of the receiving party and (c) confidential but access permitted to the other party. The court and stenographers normally have unlimited access. "Eyes only" procedures require counsel and/or experts to serve as the seeing eye dog for the client, a task for which counsel or experts may not be perfectly suited.

To avoid permitting the confidentiality designation to become too burdensome on the parties or the court, many protective orders require the producing party to designate in good faith and require that motions concerning confidentiality be grouped to avoid seriatim motion practice.

Protective orders typically contain rigorous restrictions on use solely for the purposes of the action. However, a court order has limitations. If a recipient disobeys the order, while the court can impose sanctions, sanctions may not effectively protect the disclosing party, because damages to it may not be recouped through sanctions levied by the court. Among the forms provided in this section are ones which include direct contractual undertakings by individual disclosees so that an aggrieved discloser could seek contractual recourse for violation of a protective order.

4 Milgrim on Trade Secrets § 14.02 (2021)

1. Confidentiality

2. Non-compete

3. Non-disclosure Agreements

4. Protective Order-preliminary or permanent injunctive relief

There is a difference between cases involving civil **discovery** and cases involving public records requests: In contrast to cases involving civil **discovery** and applying Civ.R. 26(C), a public records request is per se denied if the record meets the trade secret definition because that is the statutorily-required result under the public records act. The Revised Code and the Civil Rules, however, set forth different procedures for civil **discovery**. Both Civ.R. 26(C) and R.C. 1333.65 contemplate the disclosure of trade secret information through **discovery** as long as the secrecy of the information is preserved. Civ.R. 26(C)(7) provides that for good cause shown, the trial court may make any order that justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including that a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way. R.C. 1333.65 provides that in an action under the Uniform Trade Secrets Act, a court shall preserve the secrecy of an alleged trade secret by reasonable means that may include granting protective orders in connection with **discovery** proceedings.

Hance v. Cleveland Clinic, 2021-Ohio-1493, ¶ 1, 172 N.E.3d 478, 481 (Ct. App.)Although confidential, trade secret information is not absolutely privileged. The rules require the court to balance the need to preserve a trade secret with a party's right to discover material that is relevant and reasonably necessary. The trial court, as appropriate, may fashion a protective order which limits who may have access to the discovered evidence. The court must balance the competing interests to be served by allowing **discovery** to proceed against the harm which may result from disclosure of trade

secrets.

Hance v. Cleveland Clinic, 2021-Ohio-1493, ¶ 1, 172 N.E.3d 478, 481 (Ct. App.)

a. Sioux Pharm, Inc. v. Eagle Labs., Inc. , 865 N.W.2d 528 (Iowa 2015).

b. Layne Christensen Co. v. Purolite Co., 271 F.R.D. 240 (D. Kan. 2010), found the there was good cause for a two-tier protective order that limited disclosure

Under the UTSA, a trade secret owner may obtain injunctive relief against actual or threatened misappropriation. A prevailing owner may also be entitled to money damages. Attorney's fees are limited to cases involving the losing party's bad faith or willful conduct. The federal EEA defines criminal penalties for misappropriation, including fees and imprisonment.

I. Injunctive Relief

A trade secret owner who proves a likelihood of success, or one who has actually prevailed on a misappropriation claim, may obtain preliminary or permanent injunctive relief under the UTSA. The standard for injunctive relief uses the same four factors as in other intellectual property and civil litigation.

Because protection lasts as long as the secret, the duration of an injunction prohibiting a trade secret's disclosure or use can sometimes pose challenges. One approach that courts use is to determine the length of the head start a defendant obtained from the misappropriation. For example, a trade secret owner might plan to disclose a secret that it had developed once the owner brings a product to market. If a defendant misappropriates the trade secret during the owner's development period, an injunction might bar the defendant's use or disclosure of the secret for the length of time it would've taken the owner to develop the product and disclose the secret publicly. In that way, the injunction removes the

commercial advantage the defendant obtained improperly. Injunctions lasting for an indefinite period of time are usually invalid.

Injunctive relief prohibiting a secret's disclosure or use can also include reasonable, limited-duration restrictions on the work a trade secret owner's former employee does for a subsequent employer. One contractual tool that trade secret owners use to maintain the secrecy of valuable information is a noncompetition agreement. Usually, a noncompetition agreement prohibits a departing employee from working in a particular field for a particular length of time in a particular geography. Alternatively, an agreement might bar a departing employee from working for certain competitors for a particular length of time. To be enforceable in most states, the restrictions a noncompetition agreement places on a departing employee's work must be reasonable in scope and duration.

A court considering whether to enforce a noncompetition agreement with an injunction may enforce the agreement in full, or not at all, or reform the agreement's terms to make its scope or duration reasonable. Evidence of an employer's overreaching, coercion, or other anticompetitive conduct in the negotiation process is more likely to result in a refusal to enforce an unreasonable agreement, rather than a modification of the agreement's terms.

For example See [*Amazon.com, Inc. v. Powers*, 2012 WL 6726538 (D. Wash. 2012)], an online retailer sought to prevent a former employee from working for a particular competitor in the field of cloud computing. The former employee had signed a noncompetition agreement with two prohibitions. First, the agreement prohibited the employee from working with customers the employee had served while working at the retailer. Second, the agreement prohibited the employee from working in competition with the retailer in any capacity. Both prohibitions lasted for 18 months. The first prohibition was reasonable in scope, but not duration. Evidence indicated that the former employee's knowledge of the retailer's marketing practices would soon become outdated. Therefore, the court shortened the length of

that first prohibition from 18 months to nine months. In contrast, the scope of the second prohibition was unreasonable because it had no geographical limit. The retailer made no specific showing of how working for a competitor thousands of miles away would be unfair. As such, the court refused to enforce the second prohibition.

Several states have limited noncompetition agreements by statute. Most restrictive is California, where all noncompetition agreements are unenforceable unless they're related to the sale or dissolution of a corporation, partnership, or limited-liability corporation.

The UTSA also permits a court to award a reasonable royalty in lieu of an injunction, but only in exceptional circumstances. Exceptional circumstances include, but aren't limited to, a person's material or prejudicial change in position prior to acquiring knowledge or reason to know of a misappropriation. For example, a third party may invest in equipment and other product-development resources before acquiring misappropriated information from a defendant, without any knowledge that the information it plans to obtain has been misappropriated. A court might opt to ask that person to pay a reasonable royalty to use the information, rather than barring the information's use entirely with an injunction.

II. Money Damages

In addition to or instead of injunctive relief, a prevailing trade secret owner may also recover money damages. In UTSA jurisdictions, money damages include any losses to the trade secret owner resulting from the misappropriation, as well as any of the defendant's unjust enrichment from the misappropriation. Jurisdictions following the Restatement rather than the UTSA, such as New York, may not permit unjust-enrichment damages. If actual losses or unjust enrichment aren't measurable, then courts may instead award damages based on the defendant's payment of a reasonable royalty.

III. Enhanced Damages and Fees

Enhanced money damages and attorney's fees are recoverable if a trade secret owner can prove that the misappropriation was willful and malicious. The UTSA caps enhanced damages at twice the amount actually suffered. Conversely, a prevailing defendant unsuccessfully accused of misappropriation may recover its reasonable attorney's fees if it can prove that the trade secret owner brought its claim in bad faith. The UTSA specifies that a court, not the jury, determines whether and to what extent to award enhanced damages and attorney's fees.

IV. Criminal Penalties

Trade secret theft is also a crime under both state and federal law. At the federal level, the EEA provides for fines of up to $500,000 for individual defendants and $5 million for corporate defendants. Individuals may also receive prison sentences of up to 10 years.

III. Emerging Issues as Reflected in Litigation (what you might be forced to disclosed in litigation) see FDA filings, big discovery fights, two layers of protective orders, discovered but layered and kept confidential, force discovery but allow only outside council to see, polymorph cases patent cases, inhouse lawyers shouldn't be allowed to see these things because of involvement, inhouse lawyers might be talking to regulatory groups. Not fair to make their challenges via the FDA.

A. Obtaining Trade Secret Protection

Trade secret law protects valuable information, so long as its owner makes reasonable efforts to maintain the information's secrecy. Trade secret protection is available under both state and federal law. The vast majority of states have adopted some version of the Uniform Trade Secrets Act, or UTSA. In 2016, Congress enacted the Defend Trade Secrets Act, or DTSA, which added federal protection for trade secrets based largely on concepts developed by state law.

The UTSA and the DTSA define a trade secret nearly identically. First, a trade secret is any information that derives independent economic value from being secret. Second, an owner must take reasonable measures to maintain the information's secrecy. There's no registration or examination system for trade secrets. To obtain trade secret protection for qualifying information, an owner must make reasonable efforts to maintain the secrecy of protectable information.

I. Information Deriving Independent Value from Its Secrecy

Protectable information may take a variety of forms, including formulas, patterns, programs, devices, methods, techniques, or processes. Protectable information doesn't necessarily have to be complex or highly technical. Unlike patentable inventions, trade secrets don't have to be new or novel to be protectable. Someone other than the owner may have thought of or may also be using protectable information.

To be eligible for protection, information must derive independent economic value from being secret. Trade secrets give their owners advantages over competitors who don't know the protected information. To show the information's value, an owner may prove the competitive advantages of its secret information in the business. That value could also consist of negative information, for example, the knowledge that a process or technique or technology won't work. In other words, the information's value lies in the facts that it's **not generally known to others and not readily ascertainable to others using proper means**.

Information that's generally known or easily figured out by others using proper means isn't protectable. For example See [*Buffets, Inc. v. Klinke*, *73 F.3d 965 (9th Cir. 1996)*], an owner of a chain of buffet restaurants sued a competitor for trade secret misappropriation. The owner argued that the competitor had stolen the chain's secret recipes for barbecue chicken and macaroni and cheese. The recipes, while detailed, were typical American fare widely used in many restaurants and easily

obtainable. Because the recipes were generally known and readily ascertainable by others, they couldn't be protected as trade secrets.

II. Reasonable Efforts to Maintain Secrecy

An owner obtains trade secret protection for eligible information by making reasonable efforts to keep the information secret. Absolute secrecy isn't required. Rather, an owner's efforts at maintaining secrecy must be reasonable under the circumstances. These efforts might center around storing information securely, limiting access to information, and requiring persons with access to sign nondisclosure or confidentiality agreements.

An owner isn't required to undertake extreme or unduly expensive security practices or to guard against flagrant industrial espionage. But reasonable efforts are required. For example See [*Electro-Craft Corp. v. Controlled Motion, Inc.*, 332 N.W.2d 890 (Minn. 1983)] , a trade secret owner's physical plant had a few guarded entrances but several unlocked entrances with no signs warning about limited access. Over time, the owner stopped enforcing its requirement that employees wear badges. Drawings and plans containing proprietary information were discarded in the trash but not destroyed. Although some research notebooks were kept in locked drawers, others weren't kept in a locked or central location. The owner didn't limit employee access to documents containing propriety information. None of the owner's technical documents were marked confidential, and all were routinely sent to customers and other third parties. The owner also provided many informal tours of its facilities to third parties without warnings about confidential information. This evidence supported a conclusion that the owner didn't take reasonable steps to maintain the information's secrecy.

Determining whether an owner has taken reasonable steps to maintain the information's secrecy is necessarily a fact-intensive inquiry that, if disputed, doesn't lend itself to resolution at summary judgment.

III. Disclosure Ends Trade Secret Protection

An owner's trade secret protection lasts potentially indefinitely, for as long as the information remains secret. Public disclosure of a trade secret ends an owner's protection. In general, trade secret information might be disclosed in a variety of ways, including intentionally or inadvertently by the owner herself, or by a third party.

For example, a trade secret owner may voluntarily disclose information in a patent application. In general, the choice between trade secret and patent protection is binary. Once information is disclosed publicly in a published patent application, it can't be maintained as a trade secret. Most patent applications are published 18 months after being filed, before an applicant knows for certain whether any patent rights will issue from the application. The choice to pursue patent protection over maintaining information as a trade secret therefore involves some risk.

A government might also compel disclosure from an owner. For example, health and environmental regulations might require the disclosure of a product's ingredients. Different agencies have different procedures for handling proprietary or trade secret information. The United States Supreme Court has concluded See ***Ruckelshaus v. Monsanto Co.,*** that federal requirements that private parties disclose trade secrets may constitute a taking under the Fifth Amendment that requires compensation.

A trade secret owner might inadvertently or accidentally disclose trade secret information. For example, proprietary sketches or research notes might be misplaced or left in a public place. In general, the extent of the public disclosure determines whether trade secret protection continues after an accidental disclosure. Under the UTSA, it's misappropriation for someone to then disclose a trade secret that the individual knows has been acquired by accident or mistake.

Trade secret protection might also end with a third party's public disclosure. For example, a third party might independently develop or discover the secret, and then publicly disclose it. This public disclosure

destroys any trade secret protection anyone, either the third party or the earlier owner, might seek for the publicly disclosed information.

B. Trade Secret Misappropriation

Misappropriation of a trade secret is a tort that may occur in several ways. One is when an individual acquires the trade secret through improper means, such as theft, bribery, misrepresentation, or espionage.20 Another is when the individual uses or discloses the trade secret through a breach of confidence. For example, an employee might switch jobs and then disclose his previous employer's trade secrets in violation of a confidentiality agreement.21 Finally, a trade secret may be misappropriated if it is used or disclosed with knowledge that the trade secret had been acquired improperly or through mistake. A person who uses information that he knows to have been stolen by another is therefore also guilty of misappropriation.22 It is not a violation of trade secret law for another party to independently develop the subject matter of a trade secret, or for a party to analyze publicly available products or information in order to discover the secret information.23 In addition, "reverse engineering," which involves "starting with the known product and working backward to divine the process which aided in its development or manufacture," is not considered an improper means of acquiring the subject matter of another's trade secret. 24 Misappropriation of a trade secret may be enjoined by a court and the defendant may also be liable for compensatory and punitive damages.25

(Restatement (Third) of Unfair Competition §40 (1994). 21 See Jennifer Brockett, Protecting Intellectual Property During Layoffs, 32 LOS ANGELES LAWYER (April 2009). 22 Restatement (Third) of Unfair Competition §40 (1994). 23 Id. at §43.)

C. Trade Secret Remedies

D. Issues in Discovery: qualified evidentiary privilege for trade secrets.

Preserving Trade Secrets at District Court Hearings and Trials

Trade secret owners who decide to enforce their rights in court must demonstrate that they took reasonable measures to protect their trade secrets. Frequently, however, trade secret owners enforcing their rights are required to disclose their trade secrets to the court.[1] How can a trade secret owner continue to protect its trade secrets when it has to reveal them to the judge, jury, and potentially everyone else in the courtroom? Here we discuss some best practices for preserving trade secrets at federal district court hearings and trials.

Trade Secret Protection through Sealing Court Records

Trade secrets identified in pleadings and other documents filed with the court may be protected by sealing these filings. Many district courts have local rules setting forth procedures for filing documents under seal. See, e.g., C.D. Cal. Civil L.R. 79-5; N.D. Cal. Civil L.R. 79-5; E.D. Tex. L.R. CV-5(a)(7); W.D. Tex. L.R. CV-5.2.

To seal a filing, a party must overcome the presumption of public access to judicial records. Trial courts have discretion to decide whether to seal court records, and in making this determination, courts "balance the public's common-law right of access against interests favoring nondisclosure." 360 Mortgage Grp., LLC v. Bivona-Truman, No. 1:14-CV-847-SS, 2016 WL 7616575, at *1 (W.D. Tex. May 24, 2016); see also Hebert v. Unum Group, No. 4:18-CV-00910-SDJ-KPJ, 2020 WL 4922117, at *2 (E.D. Tex. Aug. 21, 2020) ("Ultimately, the decision whether to allow public access to court records is left to the 'sound discretion of the trial court … to be exercised in light of the relevant facts and

circumstances of the particular case.'" (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 599 (1978))).

Generally, "the greater the public interest in the litigation's subject matter, the greater the showing necessary to overcome the presumption of access." Shane Grp., Inc. v. Blue Cross Blue Shield of Michigan, 825 F.3d 299, 305 (6th Cir. 2016). For example, the Eastern and Western Districts of Texas apply a greater burden to requests to seal dispositive filings compared to requests to seal non-dispositive filings. Because the public's interest in non-dispositive matters is relatively low, to seal a non-dispositive filing, a trade secret owner "need only demonstrate 'good cause.'" 360 Mortgage Grp., 2016 WL 7616575, at *2 (citing Pintos v. Pac. Creditors Ass'n, 605 F.3d 665, 678 (9th Cir. 2010)). To seal a filing that addresses a case-dispositive issue, however, a trade secret owner must "provide sufficiently compelling reasons to override the presumption of public access to court." Id. Courts applying both standards have granted motions to seal "when necessary to ensure that [judicial] records … are not used 'as sources of business information that might harm a litigant's competitive standing.'" Hebert v. Unum Grp., No. 4:18-CV-00910-SDJ-KPJ, 2020 WL 4922117, at *2 (E.D. Tex. Aug. 21, 2020) (quoting Bianco v. Globus Med., Inc., No. 2:12-CV-00147-WCB, 2014 WL 3422000, at *1 (E.D. Tex. July 14, 2014) (quoting Nixon, 435 U.S. at 598)); see, e.g., Neon Enter. Software, LLC v. Int'l Bus. Machines Corp., No. A-09-CA-896 AWA, 2011 WL 2964796, at *1 (W.D. Tex. July 20, 2011) ("It is not uncommon for a court to seal documents filed in a case when those records contain trade secrets, sensitive commercial information, [or] privileged material …").[2]

Notably, in early 2021, district courts across the country responded to "recent disclosures of wide-spread breaches of both private sector and government computer systems" by "immediately adding new

security procedures to protect highly sensitive documents filed with the courts."[3] These new security procedures included entering orders that require parties to file certain "Highly Sensitive Documents" ("HSDs") outside of the courts' electronic filing systems.[4] The Eastern District of Texas General Order Regarding Procedures for the Filing, Service, and Management of Highly Sensitive Documents, for example, defines HSDs as documents containing "Highly Sensitive Information" ("HSI") and defines HSI as:

[I]nformation that is likely to be used by a hostile foreign government or its intelligence service to harm the interests of the United States, or likely to be used to commit foreign or domestic crimes, so that disclosure or use will cause significant harm; and any other information which, if disclosed, would pose a risk to national security, a clear and present danger to life and safety or result in grave or extreme harm.

The Eastern District of Texas General Order "anticipates that HSDs may also include documents that, in the judgment of the filing party, are or contain HSI that is substantially likely to adversely affect," inter alia, "nonpublic intellectual property, trade secrets, or highly confidential commercial information." The Eastern District of Texas General Order also anticipates, however, that many documents, including "most sealed filings in civil cases," among others, "do not contain HSI and are not HSDs" and therefore "will continue to be filed under existing sealing procedures."[5]

Closing the Courtroom to Protect Trade Secrets

A trade secret owner may be able to seal the courtroom during a hearing or trial where trade secrets are discussed, but the ability to close the courtroom varies among district courts.

Some courts are reluctant to seal the courtroom during hearings or trials where trade secrets are discussed because of the right of the public to access judicial proceedings.[6] See, e.g., 3A Composites USA, Inc. v. United Indus., Inc., No. 5:14-CV-5147, 2015 WL 11121362, at *3 (W.D. Ark. Nov. 10, 2015) (denying motion "to close the courtroom during periods of the trial where trade secret evidence is presented" because the plaintiff's "privacy interests [could] be adequately protected by sealing the exhibits that are introduced at trial for the duration of the trial"); US Investigations Servs., LLC v. Callihan, No. 2:11-CV-0355, 2011 WL 1157256, at *1 (W.D. Pa. Mar. 29, 2011) (denying motion to close the courtroom because "protection of Plaintiff's trade secrets … [could] be attained through alternatives not as drastic as closing the courtroom for the entirety of the proceeding"); see also, e.g., Barr Labs., Inc. v. KOS Pharm., Inc., 362 F. Supp. 2d 421, 423–24 (S.D.N.Y. 2005) (in a patent infringement case brought under the Hatch-Waxman Act, denying a motion to close the courtroom during a preliminary injunction hearing because the parties could adequately argue the issues at the hearing without disclosing trade secrets).

Other courts have recognized that a trade secret owner's "right to maintain the secrecy of its proprietary information outweighs the public's right to access judicial proceedings and related documents." BP Am. Prod. Co. v. Hamer, No. 19-CV-03581-CMA-STV, 2019 WL 7049990, at *2 (D. Colo. Dec. 23, 2019) (restricting public access to a hearing in a trade secret misappropriation case regarding the trade secret owner's motion for preliminary injunctive relief); see, e.g., United States v. Zhang, 590 F. App'x 663, 667 (9th Cir. 2014) (in a criminal theft of trade secrets case, affirming district court's decision to

close the courtroom for one witness's testimony "about the contents of the very documents that the government alleged to contain trade secrets"); Uni-Sys., LLC v. U.S. Tennis Ass'n, Inc., No. 17 CV 147 (KAM) (CLP), 2019 WL 3753780, at *4 (E.D.N.Y. Aug. 8, 2019) (finding that avoiding disclosure of a trade secret constitutes "good cause to maintain the confidentiality of the information, outweighing the public's presumptive right of access"); CDA of Am. Inc. v. Midland Life Ins. Co., No. 01-CV-837, 2006 WL 5349266, at *13 (S.D. Ohio Mar. 27, 2006) (granting motion to close the courtroom and seal the trial transcript only for "portions of the trial in which parties testify as to what they allege to be a 'trade secret,'" and not for "portions of the trial unrelated to testimony of Plaintiff's alleged 'trade secret'").[7]

How to Protect Trade Secrets in an Open Courtroom

If a motion to close the courtroom is denied, a trade secret owner may take other precautions to limit the disclosure of its trade secrets in the open courtroom.

Limiting Disclosure to the Judge and Jury: At a hearing, a trade secret owner may be able to limit disclosure of its trade secrets to the judge only, and during a trial, a trade secret owner may be able to limit disclosure of its trade secrets to the jury only. For example, at trial, a trade secret owner may be able to publish its trade secrets to screens that are viewable only by members of the jury, to establish that the trade secrets exist, without displaying the trade secrets on a screen that the entire courtroom can see.

Limiting Witnesses' Testimony: If a witness must testify about the trade secrets at a hearing or trial, a trade secret owner may be able to limit the witness's testimony to an appropriate level of generality. Trade secret owners should also consider moving to seal portions of the transcript before it is transcribed and filed in the clerk's record, rather than waiting until after the transcript is filed. See generally, e.g., Gates Rubber Co. v. Bando Chem. Indus., Ltd., 9 F.3d 823, 848–49 (10th Cir. 1993) (in a trade secret misappropriation case where the trade secrets were revealed during the course of a permanent injunction hearing, holding that the trade secret owner's post-hearing measures to protect the confidentiality of the trade secrets—having counsel monitor the presence of observers in the courtroom during the hearing, having the hearing record placed under seal after the hearing was completed, and moving to place certain exhibits on appeal under seal—were adequate to maintain the secrecy of the trade secrets).

Sealing Exhibits: At a hearing or trial in an open courtroom, a trade secret owner may also be able to limit disclosure of its trade secrets by sealing exhibits that contain trade secrets. Trade secret owners should consider moving to seal the exhibits before they are marked or discussed. Parties may also decide to agree to a pre-admitted list of exhibits prior to a hearing or trial so that an exhibit is more likely to be admitted into evidence with limited open-court discussion. See generally, e.g., Gates Rubber Co., 9 F.3d at 848–49 (finding that moving to place certain exhibits on appeal under seal, along with other post-hearing measures to protect the confidentiality of the trade secrets, were adequate to maintain the secrecy of the trade secrets).

Orders to Preserve Confidentiality Under the Defend Trade Secrets Act

For a misappropriation claim brought under the Defend Trade Secrets Act of 2016 (DTSA), a trade secret owner can seek an order to preserve confidentiality under 18 U.S.C. § 1835.[8] Section 1835 requires the court in a DTSA proceeding to "enter such orders and take such other action as may be necessary and appropriate to preserve the confidentiality of trade secrets, consistent with the requirements of the Federal Rules of … Civil Procedure, the Federal Rules of Evidence, and all other applicable laws." 18 U.S.C. § 1835(a). Additionally, "[t]he court may not authorize or direct the disclosure of any information the owner asserts to be a trade secret unless the court allows the owner the opportunity to file a submission under seal that describes the interest of the owner in keeping the information confidential." Id. § 1835(b).

District courts applying 18 U.S.C. § 1835 have limited access to hearings to only court personnel and the parties—along with their attorneys, agents, representatives, and witnesses—and have allowed documents and exhibits containing trade secrets to be filed under seal. See, e.g., BP Am. Prod. Co., 2019 WL 7049990, at *2 (restricting public access to a hearing on the plaintiff's motion for preliminary injunctive relief, and restricting public access to exhibits containing details of the plaintiff's alleged trade secrets); ZUP, LLC v. Nash Mfg., Inc., No. 3:16-CV-125-HEH, 2016 WL 11082038, at *1 (E.D. Va. Oct. 27, 2016) (granting motion to seal several documents containing purported trade secrets).

Conclusion

Trade secret owners may protect their trade secrets at federal district court hearings and trials by sealing filings that contain trade secrets, closing the courtroom when trade secrets are being discussed, and/or seeking an order to preserve confidentiality under the DTSA. If a trade secret owner is unable to seal the courtroom at a hearing or trial where trade secrets are discussed, it should consider limiting the

disclosure of the trade secrets to only the judge and members of the jury, limiting witnesses' testimony to an appropriate level of generality, and sealing exhibits that contain trade secrets.

[1] See, e.g., MAI Sys. Corp. v. Peak Comput., Inc., 991 F.2d 511, 522 (9th Cir. 1993) (holding that failure to specifically identify the trade secrets at issue precluded finding that the trade secrets had been misappropriated); see also, e.g., KLA-Tencor Corp. v. Murphy, 717 F. Supp. 2d 895, 906 (N.D. Cal. 2010) (following MAI Systems, and finding that, because "Plaintiff has not specifically identified what it considers a trade secret, instead referring to broad categories of information … the court cannot determine what is or is not a trade secret, and consequently it is impossible to render summary judgment that any trade secrets were misappropriated"); Keywords, LLC v. Internet Shopping Enters., Inc., No. CV 05-2488 MMM (EX), 2005 WL 8156440, at *17 (C.D. Cal. June 29, 2005) (following MAI Systems, and finding that, because the plaintiff "failed to identify what portions of the source codes constitute trade secrets," the court "cannot determine whether they meet the [Uniform Trade Secrets Act]'s definition of a trade secret").

[2] See also, e.g., Valley Broadcasting v. U.S. District Court, 798 F.2d 1289, 1294 (9th Cir. 1986) (recognizing an exception to the public's right of access to judicial records when a case involves trade secrets); Brown & Williamson Tobacco Co. v. FTC, 710 F.2d 1165, 1180 (6th Cir. 1983) (same).

[3] E.D. Texas General Order Regarding Procedures for the Filing, Service, and Management of Highly Sensitive Documents (Jan. 19, 2021); see also Judiciary Addresses Cybersecurity Breach: Extra

Safeguards to Protect Sensitive Court Records (Jan. 6, 2021); Highly Sensitive Document Procedures and Court Orders (last updated Mar. 9, 2021).

[4] E.D. Texas General Order Regarding Procedures for the Filing, Service, and Management of Highly Sensitive Documents (Jan. 19, 2021); see, e.g., D. Mass Order Regarding Highly Sensitive Documents Filing, Service, and Management (Jan. 26, 2021) (defining HSDs as "[d]ocuments where disclosure would breach national security" and documents "that a party believes contain[] information that is so sensitive that disclosure would cause a high risk of imminent and extreme harm to an identifiable person or entity," among others, and noting that "sealed filings in many civil cases" "generally are not considered HSDs"); S.D.N.Y. Procedures for the Filing, Service, and Management of Highly Sensitive Documents (Jan. 8, 2021) (defining HSDs as documents that "contain[] classified information or information that could harm national security" or whose "disclosure could reasonably be expected to cause exceptionally grave damage or injury to any person, entity or institution"); see also, e.g., N.D. Cal. Notice Regarding Highly Sensitive Documents (defining HSDs "as only a subset of sealed documents filed by the criminal division of the U.S. Attorney's Office," and stating that "[t]here will be no official changes to court procedure, except with respect to U.S. Attorney's Office filings").

[5] E.D. Texas General Order Regarding Procedures for the Filing, Service, and Management of Highly Sensitive Documents (Jan. 19, 2021).

[6] For example, in the Third Circuit, a party seeking to close the courtroom during a hearing "bears the burden of showing that the material [that will be disclosed at the hearing] is the kind of information that

courts will protect and that there is good cause for the order to issue." Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1070–71 (3d Cir. 1984). Generally, when a party seeks to protect its "interest in confidential commercial information, such as a trade secret, [ ] there is a sufficient threat of irreparable harm," however, to show good cause for issuing the order to close the courtroom. Id. (citing Stamicarbon, N.V. v. Am. Cyanamid Co., 506 F.2d 532, 539–42 (2d Cir. 1974)).

[7] See also, e.g., Richmond Newspapers, Inc. v. Virginia, 448 U.S. 555, 600 n.5 (1980) ("The preservation of trade secrets, for example, might justify the exclusion of the public from at least some segments of a civil trial.") (Stewart, J., concurring); Woven Elecs. Corp. v. Advance Grp., Inc., 930 F.2d 913 (Table), 1991 WL 54118, at *6 (4th Cir. 1991) (holding that the "district court should review the entire record of the trial, including the exhibits and transcripts if any, and seal [the] portions necessary to prevent the disclosure of trade secrets," and noting that it "would have been proper" for the district court to close the courtroom at trial "during the times when trade secrets were to be exposed"); Encyclopedia Brown Prods., Ltd. v. Home Box Office, Inc., 26 F. Supp. 2d 606, 612 (S.D.N.Y. 1998) ("Potential damage from release of trade secrets is a legitimate basis for sealing documents and restricting public access during trial." (citing Nixon, 435 U.S. at 598)); Uniroyal Goodrich Tire Co. v. Hudson, 873 F. Supp. 1037, 1040 (E.D. Mich. 1994) (in a trade secret misappropriation case, noting that the court had previously granted the plaintiff's request to close the courtroom at trial), aff'd, 97 F.3d 1452 (Table), 1996 WL 520789 (6th Cir. 1996) (per curiam); Standard & Poor's Corp., Inc. v. Commodity Exch., Inc., 541 F. Supp. 1273, 1278 (S.D.N.Y. 1982) ("To have refused to close the proceedings during the testimony concerning the trade secrets would have … put [the plaintiff] to the Hobson's choice of not suing [the defendant] for … use of its trade secrets … or suing and losing forever all the proprietary value of [its trade secrets].").

[8] Section 1835 was enacted as part of the Economic Espionage Act of 1996 ("EEA"). The EEA made the theft or misappropriation of a trade secret a federal crime. 18 U.S.C. §§ 1835–1839. The DTSA extended the EEA, creating a federal private civil action for trade secret misappropriation. Id. § 1836(b).

An Epic Trade Secret Mistake? Why Third Parties to Litigation May be at Risk of Losing Trade Secret Protections

June 7, 2021

By Carolyn Wimbly Martin and Robert Piper

Internet and Social Media + Trademarks and Brand Protection

May 21, 2021 marked the end of an epic three-week trial, pitting Epic, the owner and developer of the wildly popular Fortnite video mobile game, against Apple, the maker of the number one smartphone platform in the U.S. Despite being an antitrust case, Epic v. Apple inadvertently raised a serious trade secret concern on its very first day. On Monday, May 3 the court released a tranche of documents to the public. Many of these documents contained unredacted trade secrets owned by third parties with which each company had business relationships. Before the court could delete and reupload redacted versions of the files, journalists downloaded, read and published stories on the trade secrets contained within. The affected companies were outraged and quickly filed an avalanche of motions to seal. Although the issue would be resolved within hours, the damage was already done. Did the widespread publishing of these trade secrets render them unprotected?

Trade Secrets in the Video Game Business

A trade secret is broadly defined as any type of information that is kept secret and has economic value because it is kept secret. With limited exceptions, as soon as a trade secret is made public, it loses all protections. Owners of trade secrets mainly enforce the protection of their information through civil suits in state or federal court. A court can protect the plaintiff by ordering a defendant to cease use of the information or to protect the information from being revealed to the public. In some extreme scenarios, courts may order the seizure of the misappropriated trade secret. If the plaintiff proves that its secret has been stolen or misappropriated, the court may award monetary damages, attorneys' fees and a permanent injunction.

The video game industry is experiencing rapid growth, seeing exponential gains in sales over the last decade. In 2020 the industry generated more than $175 billion, a 20% increase over 2019. With such significant potential cashflow on the line, video game companies often go to great lengths to keep their development plans, best practices and source codes secret. Moreover, video game development requires more secrecy because of the extended development period compared to other media, such as movies. Product announcements are a major part of the marketing push and are usually timed close to product release for maximum impact. Non-disclosure agreements, intense cybersecurity and redacted documents are common ways video game corporations keep their proprietary information from leaking to their competitors or the public.

One of the fastest growing areas is mobile gaming. Fortnite, PUBG, Candy Crush, Among Us and an assortment of other titles exploded in popularity between 2010 and 2020. The video game developers must sign contracts with the platform owners (Apple for iOS and Google for Android) to place their games in the mobile App Store. Often these agreements contain, or at least reference, confidential

business plans, fee structures or other development ideas that the developer regards as its trade secrets. The developer and the platform host both understand that these secrets must be kept confidential in order to keep their trade secret status. Unfortunately, due to human error, these secrets can be leaked through sloppy e-filing when one of the platforms is taken to court.

Epic v. Apple Lawsuit Basics

Apple owns and operates iOS, which is the most popular smartphone platform in the U.S. and the second most popular phone platform in the world. Apple restricts the user's ability to download apps from outside sources, rendering the Apple App Store the only place where iPhone users can download apps. Further, Apple takes a 30% cut of any transaction that happens in an app on the iPhone. For example, every time an iPhone user buys Candy Crush gold coins, pays to remove annoying pop-up ads or upgrades their Spotify account to Premium, Apple takes 30% of the money that changes hands. Many mobile game developers see this practice as anti-competitive and have alleged violations of various antitrust and anti-monopoly laws.

Epic is the owner and developer of several popular mobile games, including its flagship property Fortnite. On average, Fortnite generates about $5 billion in profits each year, and 30 cents of every dollar spent in the iOS version of Fortnite goes straight to Apple. Last summer Epic updated the Fortnite iOS app to let users bypass the Apple pay system, allowing Epic to avoid the 30% "Apple tax." Apple responded by banning Fortnite from the App Store until Epic agreed to disable the new payment scheme. Epic filed suit in the Northern District of California ("NDCA"), alleging violations of antitrust laws and seeking a return of Fortnite to the App Store.

Third Parties Had Potential Trade Secrets Leaked Via the Public Record

As part of the discovery plan, each party agreed to release documents related to Fortnite, the App Store and any other business dealings that related to those two topics. Epic needed to provide any agreements or emails between itself and other platform hosts like Sony or Microsoft. Apple was required to produce documents related to other major game developers who partnered with the App Store.

On May 3, a significant number of these documents were made public through the online cloud storage folder on the NDCA's website. Third party corporations like Samsung, Walmart and Sony all quickly realized that documents they thought were confidential were available for the public to download. Reporters from outlets like The Verge and IGN quickly downloaded and combed through the documents, publishing multiple stories on once-confidential business plans. By the end of the day many of the documents had been deleted, redacted and reuploaded, but the damage was done.

These third party entities were outraged and began filing motions to seal documents and redact information. The inundation of motions led Judge Gonzalez Rogers to state with exasperation "I have received — I don't know what, ten? — motions from third parties asking me to seal information." These motions came so quickly, and in such large volume, that Epic's counsel had to object mid-questioning to prevent Apple from disclosing information a third party, Paradox, desired to keep confidential. When Apple's counsel retorted that this was the first time he had been alerted to Paradox's request, Epic shot back that they had just been informed themselves. Judge Gonzalez Rogers

then declared that Paradox had not filed any motion to seal the document, and that Apple could continue.

Did Sony, Microsoft and Others Lose their Trade Secret Protections When These Documents were Published?

One of the key attributes of a trade secret is that it is kept secret. In most cases a trade secret loses its status as soon as it is no longer confidential. Here, multiple outlets reported on potential trade secrets before the documents could be sealed. Media outlets reported on Sony's initial reluctance (and ultimate acquiescence) to allow cross-platform play on the PlayStation, Walmart's desire to bring its own streaming video game product to market and Microsoft's business plan to purposely lose money on sales of the Xbox. In most cases, these companies would no longer be able to enforce trade secret protections on these plans in court. However, multiple circuit courts have recognized an exception to this rule that should apply in this scenario.

According to several Circuit and District courts, the inadvertent disclosure of a trade secret at trial does not automatically destroy confidentiality. See, e.g., Hoechst Diafoil Co. v. Nan Ya Plastics Corp., 174 F.3d 411, 418 (4th Cir. 1999); The Gates Rubber Co. v. Bando Chemical Industries, Ltd., 9 F.3d 823, 848-849 (10th Cir. 1993); Religious Technology Ctr. v. Netcom On-Line Comm. Servs., Inc., 923 F. Supp. 1231, 1255 (N.D. Cal. 1995). In those cases, the court considered a variety of factors ranging from how and when the documents were made public to the measures the affected business took to protect the secret after the initial leak. The fact that the documents were inadvertently made public was just one non-dispositive factor. In each case the court found that the information could still be considered a trade secret despite being made available to the public through the court record.

The one distinction between the present circumstances and the previous case law is that the Epic v. Apple suit leaked the secrets of third parties. In each case cited above, the party at risk of losing its secrets was the party that made the e-filing mistake. Here, Sony, Walmart and Microsoft were not responsible for the inadvertent disclosure of their business secrets. In fact, it is unclear who exactly is to blame for the mishap; Epic, Apple and the court all had the potential to make this error. Regardless of which entity improperly redacted the documents, it is clear the blame does not fall on the third parties. This fact, combined with the flood of motions to seal following the inadvertent disclosures, supports a finding that the third parties were not responsible for this mistake and should not lose their trade secrets.

While the Third Parties in this Suit Should Not Worry About Their Trade Secrets, Plaintiffs and Defendants Should Still Exercise Greater Caution When E-Filing

Although multiple circuits would likely find that the third parties did not lose their trade secrets, there are still several circuits where this would be an issue of first impression. Given that there is still a possibility for a circuit split on the issue, parties to a suit should exercise great caution when e-filing discovery documents. It is entirely possible for a circuit lacking any precedent in this area to rule that the trade secrets lost protection after being so widely published. Indeed, each case cited above includes dicta that a trade secret that is inadvertently revealed through a court record and widely publicized by the press could lose trade secret status. The District Court for the Eastern District of Virginia made this exact ruling in Religious Technology Center v. Lerma, 908 F. Supp. 1362 (E.D. Va. 1995). If the mistake could be traced back to one of the parties, it could be liable to the third party for leaking the trade secrets. For this reason, it is always advisable to ensure that any request for confidentiality is honored before e-filing documents for the public record.

The Rapacke Law Group uses its litigation and intellectual property expertise to protect its clients' most important trade secrets.

A company's success is closely tied to its ability to protect its intellectual property and trade secrets. That's why it's critical to work with a legal partner with extensive experience in the highly specialized area of trade secret litigation.

What is Trade Secret Litigation?

Trade secret litigation involves a company's or individual's most confidential technical, financial, or business information, which the company or individual considers its "trade secrets." For example, the formula for Coca-Cola has been protected as a trade secret for over 100 years. Trade secret cases often involve a former employee who takes his or her former employer's proprietary information and discloses it to his or her new employer, which is frequently a competitor. Or the case may involve two companies to a joint venture who exchange trade secrets under non-disclosure agreements, and one company later decides to go on its own while using the other company's confidential information. In today's digital age, trade secrets are increasingly stolen by malicious hacking into a competitor's network infrastructure.

The biggest challenge for trade secret owners often is maintaining the secrecy of the trade secret. Once sensitive financial or business information is publicly disclosed, its value as a trade secret may be worthless. No amount of damages from a successful lawsuit may ever remedy the loss. For this reason, when trade secret theft is suspected, the owner must act expeditiously to obtain a temporary restraining order or preliminary injunctive relief to prevent the trade secret from being further exposed. Where the trade secret is kept electronically, lawyers often request the Court to appoint a forensic examiner to investigate the extent of the theft. A swift preliminary investigation can form the basis to then request the Court to take action to seize or thwart any further dissemination.

For an accused misappropriator, or for an employer who is alleged to have hired an accused misappropriator, engaging a forensic expert and commissioning a thorough internal investigation may prove critical to gathering evidence and establishing defenses. In addition to potential civil liability, criminal exposure is a serious risk under federal statutes such as the Economic Espionage Act and the Computer Fraud and Abuse Act. Mounting a robust defense on both civil and criminal fronts simultaneously requires experienced counsel with a strategic eye toward favorable resolution.

Once in litigation, the case often centers on whether the alleged trade secrets actually qualify for protection, whether they were misappropriated, and whether the trade secret owner suffered damages from any misappropriation. To qualify for protection, trade secret owners must prove that they took reasonable steps to protect the confidentiality of their trade secrets, such as requiring non-disclosure agreements for anyone who works with the trade secrets, and limiting the distribution of the trade secrets to the smallest group necessary. Trade secret cases frequently involve expert witnesses, who testify on issues ranging from whether the proprietary information is a trade secret to whether a trade secret was stolen by unauthorized use of a computer to the value of trade secrets and damages for their theft.

When a business is forced into litigation to protect its trade secrets, its lawyers must be careful to avoid disclosing them and accidentally undermining the intention of the lawsuit. Not only must trade secrets be vigorously defended, but special care must also be used to guard against their disclosure during litigation.

The first potential time where trade secret disclosure can occur is when the plaintiff files its petition or complaint. Since complaints are publicly available, any disclosure of business secrets within this initial pleading would publicize the very thing the plaintiff seeks to protect. As such, trade secret complaints rarely identify the trade secrets with particularity, and plaintiffs generally want to delay

such identification as long as possible. The defendant, on the other hand, will want and need to obtain a reasonably particular definition of the information plaintiff claims as its trade secrets before discovery production requires the revealing of its own secret information.

Despite this, numerous courts require trade secrets to be identified before discovery commences to "prevent trade secret related discovery from beginning before a particular trade secret has been identified." See MedioStream, Inc. v. Microsoft Corp., 749 F. Supp.2d 507, 517–8 (E.D.Tex. 2010).

Limiting The Scope of Disclosure

One commentator suggested a "workable definition might be that the plaintiff should provide the defendant with a general outline of its trade secrets sufficient to allow the defendant to assess the relevancy of the requested discovery and to assure the defendant (and the Court) that the defendant is not the victim of a fishing expedition."

At the initial stage of discovery, a plaintiff in Houston trade secrets litigation rarely knows exactly what trade secrets were stolen. But it does know what trade secrets it has, and this is the subject of the trade secret identification. To require instead, or in addition, that the plaintiff identify as discovery precisely which trade secrets the defendant actually misused would defeat discovery's very purpose, substantially increase the plaintiff's likelihood of failure, and effectively deprive the plaintiff of the benefit of discovery.

In federal court, if a competitor brings a claim of misappropriation of trade secrets against you, you have no obligation to comply with any of the rules of discovery until the other side first discloses "with reasonable particularity" the trade secrets that are at issue. If the party fails to do so but still seeks discovery, then you can bring a motion for protective order to stop the other side until it complies with its trade secret disclosure requirement.

A litigant can protect trade secrets during the discovery process through the use of confidentiality or protective orders, sealing court records, and/or limiting access to trade secrets to specified individuals involved in the litigation.

Some state legislation (in Texas for instance) creates a presumption in favor of granting protective orders to preserve trade secrets. This gives courts the power to seal filings and records, to limit disclosure of information to only attorneys and experts, and to order parties not to disclose trade secrets exposed during the course of litigation. Courts routinely issue protective orders forbidding unauthorized disclosure of trade secrets and redact their published opinions. Both the Uniform Trade Secrets Act (UTSA) and the federal Defend Trade Secrets Act (DTSA) authorize these and similar precautions to safeguard trade secrets during litigation. STOP

Trade Secret Protection

A trade secret protection plan should be in writing and reflect reasonable efforts to safeguard your organization's trade secrets. The following safety measures can be included in a trade secret protection policy:

Mark documents containing your company's trade secrets.

Disclose the least amount of information necessary. Like employees, outsiders should be given access to the least amount of information necessary to achieve your company's objectives.

Mark all confidential documents given to outsiders. The trade secrets legends discussed above are particularly important when exchanging documents with outsiders.

Require signed confidentiality agreements from all outsiders before giving them access to company trade secrets. The importance of this point cannot be overemphasized. Whether your relationship with

the outsider is new or established, and regardless of the duration of the relationship, it is essential to obtain a written confidentiality agreement.

FEBRUARY 16, 2018

PROTECTION OF TRADE SECRETS FROM LITIGATION DISCOVERY

By Mavrick Law Firm

Businesses often envision that litigation over trade secrets will generally involve a direct lawsuit by or against a person or company that steals or divulges such information in violation of a position of trust. However, trade secrets can come under attack by way of a discovery requests in litigation where the owner of the trade secret may not even be involved in the lawsuit. The following two recent appellate decisions are examples of the diligence required to safeguard trade secrets in litigation. Peter Mavrick is a Fort Lauderdale trade secret lawyer who represents businesses in trade secret litigation.

In Kelley v. Healthcare-IQ, Inc., 230 So. 3d 955 (Fla. 2d DCA 2017), former employees sued their former employer for breach of an employment contract. The former employer filed counterclaims against them alleging disclosure of its trade secrets. During discovery, the former employer served subpoenas for documents relating to the business practices of its competitor, who was the former employees' current employer. The employees asserted the trade secret privilege on its current employer's behalf. At the court hearing on the privilege, there was no evidence taken and no findings were made by the judge. Nevertheless, the trial court allowed the discovery of the trade secret information.

The employees immediately appealed to prevent the irreparable harm that the disclosure of their employer's trade secret information would cause to their employer. On certiorari review, the Appeals Court reversed the decision because the trial court failed to follow the proper procedure, which required it to examine evidence and determine the answers to the following two prongs: 1) whether the information requested is in fact a trade secret and 2) if it is trade secret information, whether there is a reasonable necessity for the requesting party to have the information.

In Niagra Industries, Inc. v. Giaquinto Electric LLC, 42 Fla. L. Weekly D2576 (Fla. 4th DCA Dec. 6, 2017), Niagra was a Defendant in a lawsuit relating to a serviceman's injury that occurred while repairing a tankless water heater that they designed. During the lawsuit, Niagra was ordered to disclose trade secret information pursuant to a protective order that limited who could view the documents. At trial, the parties stipulated to a dismissal before any of the confidential information was disclosed to the jury. However, the Plaintiff from that lawsuit filed a second lawsuit for that same injury, but against other plumbing companies. In the second lawsuit those other plumbing companies subpoenaed Niagra's trade secret information that was made available to the Plaintiff in the original lawsuit.

At the evidentiary hearing, Niagra provided testimony to support its position that its information was trade secret and that disclosure would have a devastating effect on its company. However, the other parties failed provide any evidence whatsoever. Instead, they argued that the information was necessary because the tank in question it was destroyed and thus it could not be examined and since the Plaintiff already viewed Niagra's trade secret information in the first lawsuit, he would have an unfair advantage in the second lawsuit. The trial court then ordered Niagra to produce its trade secret information to the other plumbing companies.

Niagra immediately appealed to prevent the disclosure of its trade secret information and to prevent the harm that it would cause to its business. On certiorari review, the Appeals Court quashed the lower court's order because the party seeking the documents had failed to present any evidence showing that it was reasonable and necessary for them to have the trade secret information. The Appeals Court held that if the destruction of a product were sufficient to justify breaching the trade secret privilege, then it could be breached any time a lawsuit involves a destroyed product. Also, that the mere existence of the first lawsuit was not sufficient to invade the trade-secret privilege.

In a discovery dispute, those asserting that the materials sought constitute trade secrets that are privileged from discovery bear the burden of establishing trade secret status. Conclusory statements as to trade secret factors without supporting factual evidence are insufficient to meet the burden of establishing trade secret status. In addition, the party claiming to possess a trade secret must demonstrate that it has taken some active steps to maintain its secrecy in order to enjoy presumptive trade secret status.

Hance v. Cleveland Clinic, 2021-Ohio-1493, ¶ 1, 172 N.E.3d 478, 481 (Ct. App.).

1. In re Michelin N. Am., Inc., 2016 Tex. App. LEXIS 2467. When the party resisting discovery establishes that the information constitutes a trade secret, the burden shifts to the requesting party to establish that the information is necessary for a fair adjudication of its claim or defense.

2. Jennifer S. Sickler and Michael F. Heim, The Impact of Rule 76a: Trade Secrets Crash and Burn in Texas, 1 Tex. Intell. Prop. L.J. 95, 97 (1993) (The authors conclude that Tex. Rule of Civ.

Proc. 76a poses a threat to trade secrets that are produced during discovery. Rule 76a addresses the sealing of court records.

3. The Honorable Craig Smith, Grant Schmidt and Austin Smith, Essay, Finding a Balance Between Securing Confidentiality and Preserving Court Transparency: A Re-Visit of Rule 76a and Its Application to Unfiled Discovery, 69 SMU L. Rev. 309 (2016)

4. James J. Watson, Annot., Discovery of Trade Secret in State Court Action, 75 A.L.R. 4th 1009 (1990).

Pg. 119-130 Pleading Standards

A. Pleading Standards

A trade secrets plaintiff will face different pleading standards, depending on whether the claim is pending in federal or state court. Federal courts use a notice pleading standard, meaning the complaint need only allege enough facts to give defendants fair notice of the basis of a claim that is plausible on its face, although mere conclusory allegations that mirror ITSA's statutory language are insufficient. In contrast, Illinois state courts require fact pleading, which is a more stringent standard requiring the plaintiff to allege the facts that give rise to each cause of action.

Issues of Discovery

Notice Pleading

Federal courts require notice pleading.

Under the Federal Rules of Civil Procedure, a sufficiently pled complaint provides the defendant with a notice of the claims. Rule 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007), the U.S. Supreme Court held that a complaint must provide some detail beyond

"labels and conclusions, and a formulaic recitation of the elements of a cause of action." Later, in Ashcroft v. Iqbal, 556 U.S. 662, 681 (2009), the Supreme Court further clarified that courts should not accept as true on a motion to dismiss either conclusory recitation of the elements of a cause of action or legal conclusions. Even after Twombly, however, fact pleading is not required: "[a] plaintiff must still provide only enough detail to give the defendant fair notice of what the claim is and the grounds upon which it rests . . . ." Tamayo v. Blagojevich, 526 F.3d 1074, 1083-84 (7th Cir. 2008). "'[A] complaint

. . . does not need detailed factual allegations'A complaint must always, however, allege 'enough facts to state a claim to relief that is plausible on its face,' and how many facts are enough will depend on the type of case." Limestone Dev. Corp. v. Vill. of Lemont, 520 F.3d 797, 803 (7th Cir. 2008) (quoting Twombly, 550 U.S. at 555, 570). Thus, determining whether a complaint states a plausible claim for relief is "context-specific." Iqbal, 556 U.S. at 663.

In a trade secrets case, the plaintiff generally must plead: "(1) what the trade secret at issue is, (2) its misappropriation and (3) its use in defendants' business." Sentry Pool v. Wavetec Pools, Inc., No. 07-4082, 2008 WL 3200837, at *2 (C.D. Ill. Aug. 6, 2008); see also Molon Motor and Coil Corp. v. Nidec Motor Corp., No. 16 C 03545, 2017 WL 1954531, at

*5-6 (N.D. Ill. May 11, 2017) (holding that complaint asserting DTSA and ITSA claims sufficiently alleged misappropriations where it alleged "enough to trigger the circumstantial inference that the trade secrets inevitably would be disclosed by" defendant to his new employer); C.H. Robinson Worldwide, Inc. v. Command Transp., LLC, No. 05 C 3401, 2005 WL 3077998, at *6 (N.D. Ill. Nov. 16, 2005) (complaint sufficient where it alleged how the defendants unlawfully acquired the trade secrets, described generally the trade secrets and explained how the defendants were using the trade secrets); BAB Sys., Inc. v. Pilatus Inv. Grp., Inc., No. 05 C 3038, 2005 WL 2850119, at *7 (N.D. Ill. Oct. 27, 2005) (complaint sufficient where it alleged a franchise agreement between the parties that prohibited

disclosure of plaintiff's trade secrets, that defendant acquired the trade secrets, and that defendant used the trade secrets in a competing business).

a) Conclusory allegations may be generally sufficient to plead a trade secrets claim if they put the defendant on notice of the nature of the claim.

In Lawson Products., Inc. v. Chromate Industrial Corp., 158 F. Supp. 2d 860, 864 (N.D. Ill. 2001), the plaintiff alleged that the defendant had gained access to the plaintiff's trade secrets, including customer and price lists, by hiring the plaintiff's former employees. On a motion to dismiss, the defendant argued that the information was not protectible as a trade secret and that even if it were, the plaintiff did not treat the information as secret. Id. at 864. Denying the motion to dismiss, the court stated that even if the complaint did not specifically identify the allegedly misappropriated information, reference to the customer and price lists was enough to put the defendant on notice as to the nature of the claim. Id. at 864-5. Regarding the effort to keep the information secret, the plaintiff's allegations that the information was provided only to select individuals within the company were sufficient under the federal notice pleading requirement, even though the plaintiff did not identify which individuals received what information and for what purpose. Id. at 865.

As Lawson Products illustrates, notice pleading permits conclusory allegations in pleading the existence of the trade secret, especially when the plaintiff wishes to avoid disclosing the nature of the trade secret in the complaint itself because the complaint is in the public record. See Papa John's Int'l, Inc. v. Rezko, 446 F. Supp. 2d 801, 810-11 (N.D. Ill. 2006) (complaint's "vague and conclusory" allegations were sufficient to state an ITSA claim under "liberal" federal pleading standards, even

though the complaint failed to disclose which aspects of a business's proprietary information were trade secrets that had been misappropriated).

The same standards appear to hold generally true after Twombly. In Sentry Pools, 2008 WL 3200837, at *2-3, the court held a complaint sufficiently pled a trade secrets claim where it identified the two products it claimed were trade secrets and alleged that the defendants sent "print books and manufacturer cut sheets" related to the products to the plaintiff's competitors 'without the authority and express permission of Plaintiff.'" As to the identification of the trade secrets at issue, the court stated that it was sufficient for the plaintiff to name "two specific products instead of broadly generalizing numerous products;" these allegations were enough to avoid discovery just "to discern which trade secrets were misappropriated." Id. at *3. In terms of the "use" requirement, the court noted that the plaintiff "need not provide the factual details" of its allegations in its complaint, as "[d]iscovery could reveal that Defendants provided [the print books and cut sheets] in an effort to develop a business relationship with Plaintiff's competitors. . . . All that matters is that Plaintiff has adequately claimed that Defendants sent this intellectual property to a competitor in the course of their business." Id.

Illustrative trade secret cases decided in federal court after Twombly include:

Denying Motion to Dismiss Trade Secret Claim:

Shield Techs. Corp. v. Paradigm Positioning, LLC, No. 11 C 6183, 2012 WL 4739263, at *3 (N.D. Ill. Oct. 3, 2012). Denying a motion to dismiss an ITSA claim because the trade secret allegations were "sufficient to identify

the alleged trade secrets at issue," even though they were "not as specific as they could [have] be[en]."

Dynamic Fluid Control (Pty) Ltd. v. Int'l Valve Mfg., LLC, 790 F. Supp. 2d 732, 741 (N.D. Ill. 2011). Denying a motion to dismiss an ITSA claim and holding that, at the pleading stage, identifying categories of information alleged to be at risk is sufficient to put defendants on notice of the claims.

Fire 'Em Up, Inc. v. Technocarb Equip. (2004) Ltd., 799 F. Supp. 2d 846, 850 (N.D. Ill. 2011). Denying a motion to dismiss an ITSA claim and holding that the plaintiff sufficiently identified its alleged trade secrets. In so holding, the court explained: "While it is true that specificity of concrete trade secrets is required to support a finding of misappropriation, the alleged trade secrets need not be disclosed in detail in a complaint to survive a motion to dismiss. Courts only dismiss a claim for lack of specificity on the pleadings in the most extreme cases."

Mobile Mark, Inc. v. Pakosz, No. 11 C 2983, 2011 WL 3898032, at *1 (N.D. Ill. Sept. 6, 2011). Denying a motion to dismiss an ITSA claim because even though the plaintiff did not identify "particular trade secrets," the complaint "single[d] out several specific antennas that [defendant's new employer] allegedly developed based on its use of the proprietary information." The court explained

that "ITSA plaintiffs are not required to plead highly specific facts on improper trade secret use, because such facts often will not be available before discovery."

Mainline Info. Sys., Inc. v. Benkendorf, No. 10 C 1264, 2010 WL 2011618, at *7 (N.D. Ill. May 20, 2010). Denying a motion to dismiss an ITSA claim where the plaintiff sufficiently identified its alleged trade secrets. The court rejected the defendant's argument that the plaintiff failed to specify the misappropriated trade secrets, explaining that the defendant simply ignored information in the complaint that identified the trade secrets.

Motorola, Inc. v. Lemko Corp., 609 F. Supp. 2d 760, 770 (N.D. Ill. 2009). Denying a motion to dismiss an ITSA claim, the court held that the plaintiff had sufficiently identified the trade secrets where it "identified a number of its technologies, programs, and similar materials that it has undertaken significant efforts to protect." The court reasoned that "[t]hough Motorola does not disclose the precise details of its trade secrets in its complaint, it is not required to do so, as this would result in public disclosure of the alleged trade secret."

Jano Justice Sys., Inc. v. Burton, No. 08-3209, 2008 WL 5191765, at *2- 3 (C.D. Ill. Dec. 11, 2008). The court held that a trade secrets complaint was sufficient where it alleged that a defendant "gained knowledge of proprietary information through his affiliation with [the plaintiff] and then used that information to create and run" a new company. Although the complaint was not detailed, it "suffice[d] to appraise Defendants of the conduct forming the basis of the suit," and that was all that was required.

Granting Motion to Dismiss Trade Secret Claim:

Carpenter v. Aspen Search Advisers, LLC, No. 10 C 6823, 2011 WL 1297733, at *3 (N.D. Ill. Apr. 5, 2011). The court granted a motion to dismiss an ITSA counterclaim without prejudice where the trade secret allegations, "while lengthy, provide[d] no specifics about the nature of the

confidential data for which [the counter-plaintiff] claims trade secret protection." The court explained: "A party seeking trade secret protection must do more than point to broad areas of [information] . . . and assert that something there must have been secret and misappropriated. The plaintiff must show concrete secrets."

a) Plaintiff must plead more than a repetition of statutory language.

Mere repetition of statutory language, however, will not satisfy the notice pleading standard. In Magellan International Corp. v. Salzgitter Handel GmbH, 76 F. Supp. 2d 919 (N.D. Ill. 1999), plaintiff Magellan provided the defendant, acting as a middleman, with written specifications for steel bars the defendant was to obtain from a Ukrainian steel mill. After the defendant's efforts to renegotiate aspects of the contract failed, the defendant attempted to sell Magellan's steel bars elsewhere, and Magellan sued for breach of contract and misappropriation of trade secrets. Id. at 921. The factual basis of Magellan's claim was that the steel bars were manufactured according to its "secret" specifications, but the complaint offered only conclusory allegations that these specifications were "sufficiently secret" and the "subject of reasonable efforts to maintain their secrecy." Id. at 927. The court held that mere

allegations of information being "sufficiently secret" and of "reasonable efforts" to maintain secrecy were insufficient to provide the defendant with notice of the basis of Magellan's claims. Id. Moreover, given the fact that any "secret" specifications were manifest in the steel bars that Magellan intended to sell to third parties, Magellan's allegations failed to demonstrate that it took measures to ensure the secrecy of its trade secrets and instead "clarified itself right out of court." Id.; see also:

Denying Motion to Dismiss Trade Secret Claim:

Adams v. Pull'r Holding Co., LLC., No. 09 C 7170, 2010 WL 1611078 (N.D. Ill. Apr. 20, 2010). Manufacturer alleged that its former employee accessed confidential customer and pricing information while still employed by the manufacturer, and then used that information to solicit the manufacturer's customers, suppliers, and distributors and to market the manufacturer's inventions to other companies for profit. In denying the former employee's motion to dismiss, the court explained that a trade secret claim need not contain additional detail about the "what," "where," "when," and "how" of the alleged misconduct.

Granting Motion to Dismiss Trade Secret Claim:

Woodard v. Harrison, No. 08-2167, 2008 WL 4724370, at *2-3 (C.D. Ill. Oct. 24, 2008). The court dismissed the plaintiff's ITSA claim without prejudice for failure to allege use by the defendants. Although the plaintiff sufficiently alleged the existence of a trade secret by identifying the software at issue, that it had value, and that he tried to protect its secrecy with a confidentiality agreement, the

plaintiff alleged only that the defendant "intends to use [the software] to develop his business." That showed only the plaintiff's fear that the defendant might use the plaintiff's trade secrets in his business, not that the defendant has or will do so.

Abbott Labs. v. Chiron Corp., No. 97 C 0519, 1997 WL 208369 (N.D. Ill. Apr. 23, 1997). Abbott claimed that its alleged trade secrets were

"sufficiently secret" and "the subject of reasonable efforts to maintain their secrecy and confidentiality." The court held that a complaint that fails to provide any factual allegations illustrating the plaintiff's efforts to maintain confidentiality is nothing more than pleading bare legal conclusions and insufficient to satisfy the notice pleading requirements. Even a notice pleading standard will require some factual allegations regarding the existence and secrecy of the trade secret.

b) Plaintiffs limited to trade secrets pled in complaint.

The Northern District of Illinois has limited plaintiffs to the trade secrets pled in the complaint. See, e.g., Combined Metals of Chi. Ltd. P'ship v. Airtek, Inc., 985 F. Supp. 827, 832 (N.D. Ill. 1997). The Combined Metals decision was based upon problems encountered in Thermodyne Food Service Products, Inc. v. McDonald's Corp., 940 F. Supp. 1300 (N.D. Ill. 1996). In Thermodyne, the defendants claimed the wording difference between the plaintiff's first and second amended complaints expanded the definition of its claimed trade secrets and therefore caught them by surprise. Id. at 1304-05. Noting that the defendants had waited until summary judgment to raise this issue, however, the

court held that the plaintiffs had sufficiently clarified the alleged secret to put the defendants on notice. Id. at 1304-05. To avoid repeating the confusion in Thermodyne, the Combined Metals court, ruling on a motion to dismiss, opined that disputes regarding the scope of the trade secret would no longer be tolerated beyond the pleadings stage. 985 F. Supp. at 832. Accordingly, the plaintiffs would not be allowed to change or narrow their allegations as the case progressed. Id. at 985. Note, however, that any application of this dicta from Combined Metals may be narrow given that Federal Rule of Civil Procedure 15(a) provides for liberal amendment of pleadings. See also:

Fast Food Gourmet, Inc. v. Little Lady Foods, Inc., 542 F. Supp. 2d 849, 852 (N.D. Ill. 2008). In a dispute about alleged misappropriation of frozen pizza crust recipes, the plaintiff provided a list of the specific trade secrets it was claiming during discovery at the court's request. At a later deposition the plaintiff's vice president of operations testified that the listed trade secrets included various processes and techniques that were not specifically included on the list provided. When asked whether these specific processes were trade secrets, he responded, "No." The plaintiff was later granted leave to amend its complaint, and it attempted to add several of the processes and techniques discussed during the deposition in its amendment. The defendant objected, but the court ruled that the processes identified by the vice president were admissible because the defendant was on notice about them as a result of the vice president's testimony.

c) Failing to identify trade secrets during discovery may prompt a court to preclude the plaintiff from amending its claims to add trade secrets.

Some courts have refused to allow a trade secret plaintiff to introduce new or amended trade secrets after the close of discovery. See, e.g., Fast Food Gourmet, Inc. v. Little Lady Foods, Inc., No. 05 C 6022, 2007 WL 3052944, at *6 (N.D. Ill. Oct. 18, 2007) (stating that "plaintiff should not be permitted to amend its trade secret definition after the close of discovery"); Rockwell Graphic Sys., Inc. v. Dev Indus., Inc., No. 84 C 6740, 1992 WL 162241,

at *3-5 (N.D. Ill. July 12, 1992) (excluding allegedly secret drawings raised after discovery closed). See also:

Combined Metals of Chi. Ltd. P'ship. v. Airtek, Inc., 985 F. Supp. 827, 832 (N.D. Ill. 1997). The court required a trade secret plaintiff to identify "specific, concrete secrets" in an amended claim, and, citing principles of fair notice, stated that the trade secret plaintiff would be prevented from later modifying its claim. In considering the defendant's request for greater specificity at the pleading stage, the court referenced a trade secrets case where such an identification was not made until the summary judgment stage and "the defendants were confused at the time of summary judgment as to the alleged trade secret." Having learned from that experience, the court required the identification and noted that "[t]he court will not entertain such a dispute at such a late stage in the proceeding again."

On the other hand, some courts have permitted late disclosure of trade secrets where the defendant was not harmed by the disclosure, for example, where the "new" trade secrets had been addressed during discovery. See, e.g., Cacique, Inc. v. V&V Supremo Foods, Inc., No. 03 C 4230, 2004 WL 2222270, at *5 (N.D. Ill. Sept. 30, 2004) (denying motion to strike parts of declaration submitted by plaintiff in

opposition to defendant's summary judgment motion, even though the declaration added trade secrets not specifically identified in discovery, because the trade secrets had been identified during a deposition and defendant failed to "ask any follow-up questions"); see also Baron v. Chehab, No. 05-3240, 2007 WL 3302432, at *2 (C.D. Ill. Nov. 6, 2007) (in a non-ITSA case, denying motion to strike supplemental interrogatory responses that identified additional fraud theories where the "supplemental responses [were] based on information already disclosed during discovery").

2. Illinois state courts require fact pleading.

The pleading of trade secrets in Illinois state court requires a plaintiff to support its complaint with factual allegations. Because Illinois is a fact pleading state, plaintiffs are required to set out the facts that give rise to their cause of action. Schal Bovis, Inc. v. Cas. Ins. Co., 314 Ill. App. 3d 562, 574, 732 N.E.2d 1082, 1092 (1st Dist. 1999).

a) Elements of trade secret misappropriation in Illinois.

To state a cause of action for misappropriation of trade secrets, the "plaintiff must allege facts that the information at issue was: (1) a trade secret; (2) misappropriated; and

(3) used in the defendant's business." Strata Mktg., Inc. v. Murphy, 317 Ill. App. 3d 1054, 1068, 740 N.E.2d 1166, 1176 (1st Dist. 2000) (citation omitted); see also Arcor Inc. v. Haas, 363 Ill. App. 3d 396, 400, 842 N.E.2d 265, 269 (1st Dist. 2005). But see Liebert Corp. v. Mazur, 357 Ill. App. 3d 265, 281, 827 N.E.2d 909, 925 (1st Dist. 2005) ("We believe the three elements of trade secret misappropriation .

. . are: (1) a trade secret existed; (2) the secret was misappropriated through improper acquisition, disclosure, or use; and (3) the owner of the trade secret was damaged by the misappropriation.") (citing Am. Antenna Corp. v. Amperex Elec. Corp., 190 Ill. App. 3d 535, 538, 546 N.E.2d 41, 43-44 (2d Dist. 1989)).

In Strata, the defendant, who previously worked for the plaintiff as a sales representative, resigned and accepted employment with the plaintiff's competitor. 317 Ill.

App. 3d at 1057-59, 740 N.E.2d at 1168-69. Strata brought suit alleging that customer and product information had been misappropriated. Id. On the defendant's motion to dismiss, the court held that Strata sufficiently pled the existence of its trade secrets and reasonable efforts to protect them. Id. at 1069, 740 N.E.2d at 1176. Specifically, Strata's complaint included allegations that it: (1) took considerable time, effort and money to compile its customer lists;

(2) kept the information under lock and key; (3) limited computer access; and (4) required its employees to sign confidentiality agreements. Id., 740 N.E.2d at 1176-77. Moreover, the court ruled that Strata sufficiently pled "use" of its misappropriated trade secrets by way of claiming inevitable disclosure. Id. at 1069-70, 740 N.E.2d at 1177-78 (citing PepsiCo, Inc. v. Redmond, 54 F.3d 1262 (7th Cir. 1995)).

On the other hand, in Liebert Corp. v. Mazur, 357 Ill. App. 3d 265, 281, 827 N.E.2d 909, 925 (1st Dist. 2005), the court refused to interpret Strata as narrowly "requir[ing] those claiming trade secret misappropriation to show use in every case." Noting that under ITSA's misappropriation "can be

shown one of three ways—by improper acquisition, unauthorized disclosure, or unauthorized use," the Liebert court concluded that "use" is "just one theory that can be pursued under ITSA; it is not the only theory." Id. On this basis, the Illinois Appellate Court reversed the trial court's finding that the plaintiffs failed to establish a likely claim of "misappropriation" because the defendants had not "used" the alleged trade secrets; rather, the facts alleged by the plaintiffs raised a fair inference that the defendants acquired the information through improper means, making dismissal of the plaintiffs' motion for preliminary injunction inappropriate. Id. at 283, 827 N.E.2d at 927.

b) Detail required to plead trade secret misappropriation in Illinois.

Although there is little case law discussing the detail required to plead a trade secrets case in Illinois state court, Strata may provide plaintiffs with useful guidelines. Trade secrets should be pled to a level of detail that permits drawing an analogy to circumstances where courts sustained allegations of trade secrets and reasonability of efforts of protection. See Strata, 317 Ill. App. 3d at 1069, 740 N.E.2d at 1176-77. In Strata, the plaintiff's alleged trade secret was its customer list, but the pleading included allegations that this list took considerable time, effort, and money to compile. Id. The court concluded that such details were sufficient to allege the existence of a trade secret. Id. Similarly, the court concluded that the plaintiff pled sufficient facts to illustrate its methods for maintaining secrecy—limiting computer access, requiring employees to sign confidentiality agreements, and keeping customer contracts under lock and key. Id., 740 N.E.2d at 1177.

In Alpha School Bus Co., Inc. v. Wagner, 391 Ill. App. 3d 722, 742-43, 910 N.E.2d 1134, 1154 (1st Dist. 2009), the Illinois Appellate Court affirmed the dismissal of a trade secret claim where the plaintiffs "failed to attach [to their complaint] either [the] document[s they claimed comprised trade secrets] or an affidavit indicating why the document was unavailable," as required by 735 ILCS 5/2-606 (West 2017). That statute applies any time a plaintiff pleads a claim "founded upon a written instrument." 735 ILCS 5/2-606 (West 2017). By failing to comply with the statute, plaintiffs' assertion that the information comprised trade secrets "amount[ed] to little more than a conclusory allegation, which must be rejected on a

motion to dismiss." Alpha School, 391 Ill. App. 3d at 743, 910 N.E.2d at 1154 (citations omitted).

3. The defendant's options in obtaining early disclosure of the plaintiff's trade secret.

Federal notice pleading standards do not require a plaintiff to reveal the substance of an alleged trade secret in the pleadings. See 1 MELVIN F. JAGER, TRADE SECRET LAW § 5.38 at 5-169 (West 2004) ("A plaintiff is not required to plead all facts necessary to support a trade secret claim, or to plead all of the elements of each cause of action in the complaint."). If the trade secrets claim is pled so insufficiently that the defendant is unable to identify the trade secret, however, Federal Rule 12(b)(6) entitles the defendant to seek dismissal of the plaintiff's cause of action for failure to state a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6).

Alternatively, a defendant may file a discovery motion to compel greater disclosure of the alleged trade secret. Or, the defendant may move for a more definite statement if the plaintiff's pleading is so ambiguous that the defendant cannot reasonably draft a responsive pleading. FED. R. CIV. P. 12(e). But at least one court has explained that "[m]otions for a more definite statement are generally disfavored, and are usually granted only when the pleading is so unintelligible that the movant cannot draft a response." Fast Food Gourmet, Inc. v. Little Lady Foods, Inc., No. 05 C 6022, 2006 WL 1460461, at *1 (N.D. Ill. Apr. 6, 2006) (citation omitted). In the trade secrets context, courts often deny motions for a more definite statement. See, e.g., Dick Corp. v. SNC-Lavalin Constructors, Inc., No. 04 C 1043, 2004 WL 2967556, at *12 (N.D. Ill. Nov. 24, 2004); Brown v. CitiCorp, No. 97 CV 6337, 1998 WL

341610, at *6 (N.D. Ill. June 22, 1998); see also:

Complete Bus. Solutions v. Mauro, No. 01 C 0363, 2001 WL 290196, at

*5 (N.D. Ill. Mar. 16, 2001). "Although Defendants argue [on a motion to dismiss] that CBSI merely asserts, in a conclusory fashion, that it has trade secrets, the Court finds that CBSI has adequately pled that it has confidential information and trade secrets. Indeed, the Complaint clearly alleges that, while employed by CBSI, Mr. Mauro had access to CBSI's most valuable and sensitive information, including case and client studies, customer and employee lists, market analyses, gross margins, marketing materials, pricing lists, technological research reports, and client process and operation data, all of which was confidential. Furthermore, the Complaint alleges that CBSI goes to great lengths to ensure that this material remains confidential by requiring its employees to sign non-disclosure agreements and by maintaining a company-wide limited access policy. The Court finds that CBSI has adequately pled that the information at issue is a trade secret."

It is important to note the distinction between the definiteness requirement under Rule 12(e) and ITSA's requirement that a plaintiff sufficiently identify its trade secrets. This distinction is illustrated by subsequent opinions issued in the Fast Food Gourmet case. There, the court first denied a defendant's Rule 12(e) motion seeking a more definite statement where the plaintiff had alleged that its "unique equipment, specifications, processes, formulations and techniques were trade secrets that made possible the mass production of the unique pizza crust." Fast Food Gourmet, Inc. v. Little Lady Foods, Inc., No. 05 C 6022, 2006 WL 1460461

at *1 (N.D. Ill. Apr. 6, 2006) (quotations and citations omitted). The court reasoned that the defendant could "reasonably be required to frame an answer" because the plaintiff's trade secret allegations were sufficiently clear. Id. But in a later opinion, the court explained that the denial of a motion for a more definite statement "did not mean that the trade secrets were sufficiently explicated for all purposes." Fast Food Gourmet, Inc. v. Little Lady Foods, Inc., No. 05 C6022, 2007 WL 2156665, at *6 (N.D. Ill. July 26, 2007), rev'd on other grounds, 2007 WL 3052944 (N.D. Ill. Oct. 18, 2007) (evaluating defendants' motion to bar evidence of trade secrets following plaintiff's response to interrogatories).

A plaintiff likely will have to identify its trade secrets specifically during the discovery process. "A party to a lawsuit who raises a claim or defense based on trade secret information must be prepared to disclose the information to the other party under a protective order." 1 MELVIN F. JAGER, TRADE SECRET LAW § 5.33 at 5-153 (West 2004). Federal Rule of Civil Procedure 26 allows a court to enter a protective order "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." FED. R. CIV. P. 26(c)(1)(G); see also AutoMed Techs., Inc. v. Eller, 160 F. Supp. 2d 915, 925-26 (N.D. Ill. 2001) (refusing to compel discovery until plaintiff identified more specifically which of its trade secrets were allegedly misappropriated but granting the defendant's and the third party's motions for a protective order to protect their own trade secrets that would be disclosed inevitably when they responded to plaintiff's discovery requests); Uresil Corp. v. Cook Grp., Inc., 135 F.R.D. 168, 174 (N.D. Ill. 1991) (granting motion to compel more complete interrogatory answers where the plaintiff "has not identified the components and/or concepts incorporated in the products [the plaintiff] claims [the defendant] misappropriated" and has not "identif[ied] all information and documents alleged

. . . to be confidential and to have been misappropriated by the defendant").

A similar scenario holds true for defendants in state court. A court may order pleadings that are insufficient in substance to be amended to provide a more particular statement. 735 ILCS 5/2-612 (West 2017). The defendant may also request that the pleadings be amended or the cause of action be dismissed. Id. Additionally, Illinois Supreme Court Rule 201 governs discovery in Illinois state courts and entitles the defendant to discover information relevant to a pending action's subject matter. Ill. S. Ct. R. 201(b)(1). Again, the plaintiff's specific trade secret is relevant to a misappropriation of trade secrets action.

Finally, as in federal court, either party in Illinois state court may obtain a protective order "denying, limiting, conditioning, or regulating discovery" in order to safeguard the party's confidential business information during discovery. Ill. Sup. Ct. R. 201(c)(1); see generally Hall v. Sprint Spectrum L.P., 368 Ill. App. 3d 820, 858 N.E.2d 955 (5th Dist. 2006) (discussing a trial court's discretion to enter protective orders during discovery); MBL (USA) Corp. v. Diekman, 112, Ill. App. 3d 229, 240-41, 445 N.E.2d 418, 426-27 (1st Dist. 1983)

(quoting from Illinois Supreme Court Rule 201 in affirming grant of defendant's motion in limine that required the plaintiff to identify its alleged trade secrets before questioning defendant about defendant's current methods, techniques, and processes).

1. Failing to specifically identify trade secrets may lead to summary judgment for defendant.

It is becoming increasingly common for courts to address the propriety of trade secret identification at the summary judgment stage. See Charles Tait Graves & Brian D. Range, Identification of Trade Secret Claims in Litigation: Solutions for a Ubiquitous Dispute, 5 NW. J. TECH. & INTELL. PROP. 68, 87 (2006) ("A plaintiff's failure to identify its alleged secrets during discovery can, and often does, lead to summary judgment. Courts have frequently granted summary judgment for the defense based on a failure to sufficiently identify the trade secret claims."). For example, in IDX Systems Corp. v. Epic Systems Corp., 285 F.3d 581, 583-84 (7th Cir. 2002), the Seventh Circuit affirmed summary judgment for the defendant under Wisconsin's version of UTSA where the trade secret plaintiffs' 43-page description of its alleged trade secret was "both too vague and too inclusive." See also:

Granting Defendant's Summary Judgment Motion on Trade Secret Claim:

BI3, Inc. v. Hamor, No. 08 CV 2384, 2011 WL 1231156, at *14-15

(N.D. Ill. Mar. 30, 2011). The court granted summary judgment on an ITSA counterclaim because the counter-plaintiff's allegations were not supported by sufficient evidence showing that the technologies at issue were "secret rather than general knowledge." The counterclaim alleged that the trade secrets consisted of "technologies and methodologies used to create huge numbers of relevant keywords, structure and manage campaigns and bidding, plus track and report on campaign performance for

search engine marketing campaigns." The court held that this was insufficient, highlighting the lack of "any evidence to identify the precise 'URL tracking technology' or 'elements of that system'" that were alleged in the counterclaim.

Loparex, LLC v. MPI Release Techs., LLC, No. 1:09-cv-01411, 2011 WL 1135906, at *6 (S.D. Ind. Mar. 25, 2011). Applying Illinois law, the court granted the defendants' motion for summary judgment, in part because the plaintiff failed to sufficiently identify the alleged trade secrets in its ITSA claim. The court declared one affidavit "impermissibly conclusory" and lacking in specificity because it merely claimed that the plaintiff had "a trade secret in its capacity and methods to coat specific products for customers." Another affidavit stated that the defendants "had knowledge of . . . [the plaintiff]'s proprietary Poly Formula for the FLEXcon EX liner, including knowledge of the proprietary additive on the matte side of this liner and the process for producing it." But the court held that the second affidavit also lacked sufficient specificity because "[t]he identification of a trade secret requires more than categorizing information as a formula or secret," and "[c]alling portions of it 'proprietary' doesn't help either." The court further explained that "[t]he description doesn't distinguish, as required, those portions of the formula and production process that are readily observable, from those that aren't."

Lynchval Sys., Inc. v. Chi. Consulting Actuaries, Inc., 95 C 1490, 1998 WL 151814, at *5-6 (N.D. Ill. Mar. 27, 1998). The court granted summary judgment for a trade secret defendant where the plaintiff pointed only to the defendant's technology instead of identifying alleged secrets in its own technology.

Denying Defendant's Summary Judgment Motion on Trade Secret Claim:

Motorola, Inc. v. Lemko Corp., No. 08 C 5427, 2012 WL 74319, at *17 (N.D. Ill. Jan. 10, 2012). The court denied the defendant's summary judgment motion where the plaintiff "identified its alleged trade secrets by Bates number, file type, and/or location [and] ha[d] not simply described an area of its technology."

Charles Schwab & Co. v. Carter, No. 04 C 7071, 2005 WL 2369815, at *12 (N.D. Ill. Sept. 27, 2005). The court denied the defendants' summary judgment motion where the plaintiff identified its trade secrets "by Bates number and computer file type." In so holding, the court recognized that the defendants' motion was premature because they still had an available discovery remedy.

Do it Best Corp. v. Passport Software, Inc., No. 01 C 7674, 2005 WL 743083, at *13 (N.D. Ill. Mar. 31, 2005). The court denied the defendant's motion for summary judgment even though the plaintiff identified "every line of code it developed . . . as a description of its trade secrets." In so holding, however, the court noted that the plaintiff came "dangerously close" to losing on the identification issue, but unlike other cases where trade secret plaintiffs failed to provide any specifics about their alleged secrets, the plaintiff here "did identify specific lines of code and specific software features for which it claim[ed] protection."

Nilssen v. Motorola, Inc., 963 F. Supp. 664, 673-74 (N.D. Ill. 1997). The court denied the defendant's summary judgment motion because the plaintiff sufficiently identified its trade secrets by "document[ing] each of those nontechnical items, at least to some extent, by referring to appropriate papers from the voluminous records," even though the trade secret was defined in discovery in an "amorphous" fashion.

Thermodyne Food Serv. Prod., Inc. v. McDonald's Corp., 940 F. Supp. 1300, 1304-05 (N.D. Ill. 1996). The court denied the defendants' summary judgment motion for insufficient identification where, among other things, the plaintiff attached to its amended complaint a disclosure that "identifie[d] each component" of the alleged secrets

Inevitable Disclosure Doctrine Appendix A pg 210

IV. Conclusion

V. Resources

Footnotes: Additional facts, history, issues I don't have room to touch on.

Protective Measures

Physical Security

Digital Security

Legal (Confidentiality, Non-Compete, Non-Disclosure)

Emerging Issues as Reflected in Litigation

Issues Regarding the Elements of Trade Secret Creation and Maintenance

I. Information Deriving Independent Value from Its Secrecy (many forms, can be negative (unlike patents); value lies in the facts that it's not generally known to others and not readily ascertainable to others using proper means.

II. Reasonable Efforts to Maintain Secrecy

Absolute secrecy isn't required. Rather, an owner's efforts at maintaining secrecy must be reasonable under the circumstances. These efforts might center around storing information securely, limiting access to information, and requiring persons with access to sign nondisclosure or confidentiality agreements. An owner isn't required to undertake extreme or unduly expensive security practices or to guard against flagrant industrial espionage. Determining whether an owner has taken reasonable steps to maintain the information's secrecy is necessarily a fact-intensive inquiry that, if disputed, doesn't lend itself to resolution at summary judgment.

Electro-Craft Corp. v. Controlled Motion, Inc., 332 N.W.2d 890 (Minn. 1983)] evidence supported a conclusion that the owner didn't take reasonable steps to maintain the information's secrecy. NEED BIOTECH EXAMPLE OF REASONABLE STEPS

III. Disclosure Ends Trade Secret Protection

-protection lasts potentially indefinitely, for as long as the information remains secret.

-public disclosure ends protection.

-holds value built up by medical research protecting the time and monetary investment without restricting the chance for other companies to invest in the same research.

-deters cheating further supporting investment..

Ruckelshaus v. Monsanto Co.: Government Compel Disclosure; health and environmental regulations; federal requirements that private parties disclose trade secrets may constitute a taking under the Fifth Amendment that requires compensation.

A trade secret owner might inadvertently or accidentally disclose trade secret information. For example, proprietary sketches or research notes might be misplaced or left in a public place. In general, the extent of the public disclosure determines whether trade secret protection continues after an accidental disclosure. Under the UTSA, it's misappropriation for someone to then disclose a trade secret that the individual knows has been acquired by accident or mistake.

Trade secret protection might also end with a third party's public disclosure. For example, a third party might independently develop or discover the secret, and then publicly disclose it. This public disclosure destroys any trade secret protection anyone, either the third party or the earlier owner, might seek for the publicly disclosed information.

Case List:

Sioux Pharm, Inc. v. Eagle Labs., Inc. , 865 N.W.2d 528 (Iowa 2015).

B&D Nutritional Ingredients, Inc. v. Unique Bio Ingredients, Ltd. Liab. Co. , No. 16-62364-CIV-COHN/SELTZER, 2017 U.S. Dist. LEXIS 79594 (S.D. Fla. May 24, 2017)

U.S. ex rel. Daugherty v. Bostwick Laboratories, 2013 WL 3270355 (S.D. Ohio 2013) is a *qui tam* action alleging violations of the Anti-Kickback Statute, the Stark Laws, and the False Claims

Act and relating to HIPAA issues, in which the Court did find an AEO designation was appropriate for confidential business or financial information and competitive business information.

U.S. ex rel. McDonough v. Symphony Diagnostic Services, 2013 WL 5467830 (S.D. Ohio 2013), was a False Claims Act case which was about whether a waiver occurred relating to a claim of privilege or protection of documents occurred. Neither of these cases provide relevant insight as to the issue here - whether an AEO is appropriate in a misappropriation claims case against a former employee.

Resources:

May 1, 2020

Trade Secrets Or Patents?

Source: Life Science Leader

By Mike Fuller & Kim Kennedy

https://www.lifescienceleader.com/doc/trade-secrets-or-patents-0001

September 8, 2021

Protecting Against the Risk of Trade Secret Exposure Arising from Biotech Industry Collaboration

https://www.jdsupra.com/legalnews/protecting-against-the-risk-of-trade-4642228/

Filing for a Patent Versus Keeping Your Invention a Trade Secret

by Orly Lobel

November 21, 2013

https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret

https://www.natlawreview.com/article/trade-secret-vs-patent-false-dichotomy

sometimes the court will only allow

extreme protective orders doesn't allow any inhouse only outside counsel and experts.

Case study approach. Pose hypotheticals

I. Introduction

Patent law's scheme of protection of information via this disclosure process could be seen as the opposite of trade secret protection, which attempts to retain the value of information by protecting it against public disclosure.

Finally, even if a generic manufacturer meets the FDA's definition of trade secret when submitting an ANDA and the FDA's disclosure of the information via a FOIA request is limited, both the common law right of public access 124 and discovery requeststst 125 pose additional threats for generic manufacturers who wish to protect their trade secrets

undefined

A. Reasons for transition from patent to trade secret

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs is steadily growing. 1 The pharmaceutical industry is responsible for over three million American jobs, and pharmaceutical companies invest millions of dollars in promoting the research and development of new and generic drugs. 2 In order to retain their competitive advantage, most pharmaceutical drug manufacturers seek patent protection. 3 Manufacturers have learned to think creatively, using a variety of patents--including method, design--and research tool patents--in order to fully protect their lucrative inventions. Congress encourages biomedical research and technological innovation through the patent system. 4 Congress heavily regulates the pharmaceutical industry both directly through status such as the Federal Food, Drug, and Cosmetics Act 5 and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), 6 and indirectly through regulations promulgated by the Food and Drug Administration (FDA). 7 Several volumes of the Code of Federal Regulations are specifically dedicated to describing what manufacturers must do in order to market a drug in the United States. 8

Due to recent congressional legislation and judicial decisions, however, generic drug manufacturers have lost some previously afforded patent protections, 9 specifically with respect to their bioequivalency test method patents. For example, the safe harbor provision of the Hatch-Waxman Act allows competing drug manufacturers to "borrow" information within the patents of their competitors so long as they agree to use the patents in furtherance of submitting information to the FDA. 10 Competing generic drug manufacturers, for example, can take bioequivalency tests disclosed in the [*211] applications of their competitors and use the tests to manufacturer their own generic drugs. A bioequivalency test is a method of testing a generic

drug that proves that it is equivalent to a name brand drug that has already received FDA approval. All generic drug applications must demonstrate bioequivalency, thus the tests are extremely valuable. Unfortunately, bioequivalency testing methods can be very costly and time consuming to develop, so generic manufacturers patent the tests in an effort to protect them from use by competitors. The safe harbor provision has thus thwarted the protection scheme on which generic manufacturers depended.

The Federal Circuit recently expanded the scope of the safe harbor provision in 2012 in Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc. 11 A majority of the Federal Circuit in Momenta held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented bioequivalency testing methods for pre-clinical research and manufacturing without incurring infringement liability. 12 In 2003, Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) to the FDA to market Enoxaparin, a generic version of the name brand drug Lovenox, which is used to prevent blood clots. 13 As a result of submitting the ANDA, Aventis, the manufacturer of Lovenox, sued Amphastar; after several years of expensive patent litigation, the FDA granted Amphastar's ANDA, allowing it to manufacture enoxaparin. 14 In the meantime, however, before the FDA granted Amphastar's ANDA for enoxaparin, Momenta "borrowed" Amphastar's bioequivalency test, which was publicly disclosed in Amphastar's ANDA and used the test to beat Amphastar to the market by more than a year. 15 This one year boost resulting from "borrowing" Amphastar's patent for bioequivalency allowed Momenta a monopoly on the generic market, resulting in profits of over $ 260 million per quarter. 16

This Note argues that the Federal Circuit's holding in Momenta threatens manufacturers with a devastating loss of previously available patent protection for measuring the bioequivalency of

generic drugs. The Note concludes that trade secret law is the best alternative to patent protection until Congress decides to narrow the scope of the Hatch-Waxman Act's safe harbor provision. Due to the high cost of submitting a New Drug Application or an ANDA to [*212] the FDA, generic drug manufacturers want to seek protection for their bioequivalency tests so that consumers can reap the benefits of competition. In other words, giving generic manufacturers the ability to protect their bioequivalency tests would incentivize the production of generic drugs, which would in turn benefit consumers. However, in light of Momenta, this protection is no longer available through patent law. 17 Additionally, the Federal Circuit's interpretation of Hatch-Waxman's safe harbor provision has frustrated the generic drug manufacturer's ability to protect its research and development investments. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods for bioequivalency from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect bioequivalency tests as trade secrets.

Part II of this Note first describes the FDA's method of regulating generic drugs, including the process of submitting an ANDA, to demonstrate why this process is important to the patent protection which Momenta has recently frustrated for manufacturers. This section then explains how some of the information submitted to the FDA in furtherance of the ANDA can be protected through trade secret law instead of through patent law.

Part II next reviews the relevant parts of the Hatch-Waxman Act and specifically focuses on the evolution of the safe harbor provision, codified at 35 U.S.C. § 271(e)(1). Moreover, this Part explores prior United States Supreme Court opinions leading up to Momenta which have

interpreted the safe harbor provision and demonstrates that the scope of the safe harbor provision has been expanded to such an extent that protection via method patents for bioequivalency tests is no longer available.

Additionally, Part II summarizes the current state of trade secret law and demonstrates how a bioequivalency test could qualify as a trade secret. This part also discusses the four potential threats of disclosure that a bioequivalency test trade secret could face, including FOIA requests, FDA use, and litigation; related threats, including the common law right of public access and discovery requests.

Part III argues that trade secret law is not only available to generic manufacturers but is ultimately a better alternative to protecting bioequivalency tests than patent law. Part III demonstrates how generic manufacturers can overcome threats of disclosure of their trade secrets presentation FOIA requests, FDA use and disclosure, and litigation.

NOTE: TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER MOMENTA V. AMPHASTAR

NOTE: TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER MOMENTA V. AMPHASTAR, 22 J. Intell. Prop. L. 209

1. new federal and increased common law trade secret protections

2. patents being invalidated

3. payments to avoid invalidation cases being ruled out via antitrust law

4. The need for layering of trade secrets and patents anyway for indiscrepency of what all is protected

B. But this transfer of technological protections has led to a whole new set of issues regarding legislation. How can a trade secret which depends on a lack or disclosure to maintain its value, be subjected to a system (judicial system) that requires discovery whether as a notice to the opposing party, to an evaluation of its very existence, to the judges and experts, maintain this value through litigation?

The UTSA and the DTSA define a trade secret in two parts. First, a trade secret is any information that derives independent economic value from being secret. Second, an owner must take reasonable measures to maintain the information's secrecy. There's no registration or examination system for trade secrets. To obtain trade secret protection for qualifying information, an owner must make reasonable efforts to maintain the secrecy of protectable information.

Court responsibility: There is a difference between cases involving civil discovery and cases involving public records requests: In contrast to cases involving civil discovery and applying Civ.R. 26(C), a public records request is per se denied if the record meets the trade secret definition because that is the statutorily-required result under the public records act. The Revised Code and the Civil Rules, however, set forth different procedures for civil discovery. Both Civ.R. 26(C) and R.C. 1333.65 contemplate the disclosure of trade secret information through discovery as long as the secrecy of the information is preserved. Civ.R. 26(C)(7) provides that for good cause shown, the trial court may make any order that justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including that a trade secret or other confidential research, development, or commercial information not be

disclosed or be disclosed only in a designated way. R.C. 1333.65 provides that in an action under the Uniform Trade Secrets Act, a court shall preserve the secrecy of an alleged trade secret by reasonable means that may include granting protective orders in connection with discovery proceedings.

Hance v. Cleveland Clinic, 2021-Ohio-1493, ¶ 1, 172 N.E.3d 478, 481 (Ct. App.)Although confidential, trade secret information is not absolutely privileged. The rules require the court to balance the need to preserve a trade secret with a party's right to discover material that is relevant and reasonably necessary. The trial court, as appropriate, may fashion a protective order which limits who may have access to the discovered evidence. The court must balance the competing interests to be served by allowing discovery to proceed against the harm which may result from disclosure of trade secrets.

Hance v. Cleveland Clinic, 2021-Ohio-1493, ¶ 1, 172 N.E.3d 478, 481 (Ct. App.)

TOPIC STATEMENT: Litigation of Trade Secrets are at most risk during Notice, Discovery

1. Notice Reguirment

From the very beginning of litigation, the notice requirement sets up a issues of disclosure for those who are determined to protect their trade secrets.

2. Discovery

3. Experts

4. Judiciary

5. Case documentation.

6. Public Records" Courts vary on their recognition of wether a trade secret owner's right to maintain secrecy of its proprietary information outweighs the public's rights to access judicial proceedings and related documents.

C. Judicial attempt to prevent these arms

1. Protective Orders

2. Two-tiered protection orders

Resources

NOTE: TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER MOMENTA V. AMPHASTAR, 22 J. Intell. Prop. L. 209.

EXHIBIT L

From: Williams, Laura H
Sent: Friday, January 7, 2022 3:44 PM
To: Butler, William Elliott <web15@psu.edu>; Riesmeyer, Megan <mam941@psu.edu>; M.N., A.B. AND S.R.

Cc: N.B.
Subject: RE: Honor Code Proceeding: Further Information

Dear Hearing Board Members:

One of the Hearing Board members raised a question about Prof. Gould's suggestion to run the papers through a plagiarism software program. For your reference, please refer to Section 1.1(12) of the Dickinson Law Honor Code for the definition of Plagiarism.

In furtherance of the Pre-Hearing Procedure in Section 5.4(A), I am attaching the following documents:

- Plagiarism comparison run through comparison software. I did this on Sunday as a preliminary matter.
- Using that document as a starting point, I marked the Accused Student's paper against the Law Review Note in question to show the places that it tracks the Law Review Note.
- I also marked the Law Review Note, showing the places where the student's paper corresponds thereto.

I sent the marked documents to the Accused Student on Tuesday. Furthermore, I have sent all three documents to Accused Student today, as required under section 3.1(A) of the Honor Code.

If you have questions, please let me know.

Dean Williams

Laura H. Williams
Associate Dean for Administration

Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

From: Williams, Laura H
Sent: Friday, January 7, 2022 11:32 AM
To: Butler, William Elliott <web15@psu.edu>; Riesmeyer, Megan <mam941@psu.edu>; N.B.
N.B.

Cc: N.B.
Subject: Honor Code Proceeding: Further Information

Dear Hearing Board Members:

I am the Dickinson Law Honor Code Administrator, and therefore under Section 5.3(D) of the Dickinson Law Honor Code, I am the "Presenter" for the upcoming Hearing, scheduled for January 14, 2022, at 1:00 PM in the Dickinson Law Hearing Room.

In accordance with Section 5.4 of the Honor Code, I am providing the following documents relative to the Honor Code Hearing:

1. Report of possible Honor Code violation (Prof. J. Gould)
2. Tshudy - Research Paper Final – with highlighting (from Prof. Gould)
3. Trade Secrets Rising (Law Review Note)
4. Student's email Response with marked outline

I may distribute additional information in advance of the Hearing to the extent it becomes available.

If you have questions, please let me know.

Laura H. Williams
Associate Dean for Administration
Dickinson Law
The Pennsylvania State University
150 S. College St.
Carlisle, PA 17013
717.240.5218 (o)
717.385.9783 (c)
lhw10@psu.edu

9864 words 29% matched		13089 words 21% matched
The United States has the largest and fastest growing drug market in the world , and the demand for generic drugs	<< 21 words >>	The United States has the largest and fastest growing drug market in the world , and the demand for generic drugs
millions of dollars in promoting the research and development of new and generic	<< 13 words >>	millions of dollars in promoting the research and development of new and generic
to retain their competitive advantage	<< 5 words >>	to retain their competitive advantage
most pharmaceutical drug manufacturers	<< 4 words >>	most pharmaceutical drug manufacturers
the Federal Food , Drug , and Cosmetics	<< 8 words >>	the Federal Food , Drug , and Cosmetics
and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act)	<< 17 words >>	and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act)
and indirectly through regulations promulgated by the Food and Drug Administration (FDA)	<< 14 words >>	and indirectly through regulations promulgated by the Food and Drug Administration (FDA)
the safe harbor provision of the Hatch-Waxman Act	<< 8 words >>	the safe harbor provision of the Hatch-Waxman Act
allows competing drug manufacturers to “ borrow ” information within the patents of their competitors	<< 15 words >>	allows competing drug manufacturers to “ borrow ” information within the patents of their competitors

9864 words 29% matched		13089 words 21% matched
Momenta Pharmaceuticals , Inc. v. Amphastar Pharmaceuticals ,	<< 8 words >>	Momenta Pharmaceuticals , Inc. v. Amphastar Pharmaceuticals ,
held that via the safe harbor provision , competing generic pharmaceutical manufacturers could use each other	<< 16 words >>	held that via the safe harbor provision , competing generic pharmaceutical manufacturers could use each other
testing methods for pre-clinical research and manufacturing without incurring infringement	<< 10 words >>	testing methods for pre-clinical research and manufacturing without incurring infringement
Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA)	<< 16 words >>	Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA)
holding in Momenta threatens manufacturers	<< 5 words >>	holding in Momenta threatens manufacturers
with a devastating loss of previously available patent protection for	<< 10 words >>	with a devastating loss of previously available patent protection for
safe harbor provision has	<< 4 words >>	safe harbor provision has
. Fortunately , a solution exists for generic drug manufacturers who wish to shield their tests and methods	<< 18 words >>	. Fortunately , a solution exists for generic drug manufacturers who wish to shield their tests and methods
from the hungry eyes of their competitors . Despite the numerous regulations governing disclosure of information submitted to the FDA ,	<< 46 words >>	from the hungry eyes of their competitors . Despite the numerous regulations governing disclosure of information submitted to the FDA ,

9864 words 29% matched		13089 words 21% matched
including most notably the Freedom of Information Act (FOIA) , generic drug manufacturers , using a heightened degree of care , can protect		including most notably the Freedom of Information Act (FOIA) , generic drug manufacturers , using a heightened degree of care , can protect
as trade secrets .	<< 4 words >>	as trade secrets .
, FDA use ,	<< 4 words >>	, FDA use ,
the common law right of public access	<< 7 words >>	the common law right of public access
to qualify for trade secret protection ,	<< 7 words >>	to qualify for trade secret protection ,
trade secret law originally evolved under state common law , the Uniform Trade Secrets Act (UTSA)	<< 18 words >>	trade secret law originally evolved under state common law , the Uniform Trade Secrets Act (UTSA)
information , held by one or more people , without regard to form , including a formula . . . method . . . technique	<< 25 words >>	information , held by one or more people , without regard to form , including a formula . . . method . . . technique
or process that : (1) derives independent economic value	<< 11 words >>	or process that : (1) derives independent economic value
from not being generally known to , and not being readily ascertainable by proper means by , other persons who can obtain economic value from its disclosure or use ; and is the subject of efforts that are reasonable under the circumstances to maintain its	<< 45 words >>	from not being generally known to , and not being readily ascertainable by proper means by , other persons who can obtain economic value from its disclosure or use ; and is the subject of efforts that are reasonable under the circumstances to maintain its

9864 words 29% matched		13089 words 21% matched
, each manufacturer should	<< 4 words >>	, each manufacturer should
the scope of the trade secret protection	<< 7 words >>	the scope of the trade secret protection
will make the fullest possible disclosure of records to the public , consistent with the rights of individuals to privacy , the property rights of persons in trade secrets and confidential commercial or financial	<< 34 words >>	will make the fullest possible disclosure of records to the public , consistent with the rights of individuals to privacy , the property rights of persons in trade secrets and confidential commercial or financial
Except where specifically exempt pursuant to the provisions of this part , all FDA records shall be made available for public	<< 21 words >>	Except where specifically exempt pursuant to the provisions of this part , all FDA records shall be made available for public
A trade secret may consist of any commercially valuable plan , formula , process , or device that is used for the making , preparing , compounding , or processing of trade commodities and that can be said to be the	<< 41 words >>	A trade secret may consist of any commercially valuable plan , formula , process , or device that is used for the making , preparing , compounding , or processing of trade commodities and that can be said to be the
product of either innovation or substantial effort . There must be a direct relationship between the trade secret and the productive	<< 21 words >>	product of either innovation or substantial effort . There must be a direct relationship between the trade secret and the productive
Freedom of Information Act	<< 4 words >>	Freedom of Information Act
controls the public disclosure of previously unreleased information from federal	<< 10 words >>	controls the public disclosure of previously unreleased information from federal
each agency , upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published	<< 53 words >>	each agency , upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published

9864 words 29% matched		13089 words 21% matched
rules stating the time , place , fees (if any) , and procedures to be followed , shall make the records promptly available to any		rules stating the time , place , fees (if any) , and procedures to be followed , shall make the records promptly available to any
to make as much agency information available to the public as possible ,	<< 13 words >>	to make as much agency information available to the public as possible ,
information that is “ exempted from disclosure by statute. ”	<< 10 words >>	information that is “ exempted from disclosure by statute. ”
trade secrets and commercial or financial information obtained from a person and privileged or confidential ,	<< 16 words >>	trade secrets and commercial or financial information obtained from a person and privileged or confidential ,
reasonably details the information	<< 4 words >>	reasonably details the information
the confidentiality of requested information is	<< 6 words >>	the confidentiality of requested information is
uncertain , the FDA will contact the entity who submitted the information and/or who will	<< 15 words >>	uncertain , the FDA will contact the entity who submitted the information and/or who will
be affected by its disclosure before determining	<< 7 words >>	be affected by its disclosure before determining
whether to disclose the	<< 4 words >>	whether to disclose the